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Clerk, U.S. District Court, ILCD

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLIINOIS
CIVIL ACTION NO. _____

EDWIN SPINKS, Plaintiff, vs. LivaNova PLC, Sorin Group Deutschland GMBH, and Sorin Group USA, Inc., Defendants.	**COMPLAINT**

The Plaintiff, complaining of the acts of the Defendants above-named, would respectfully show unto the Court as follows:

PARTIES TO THIS ACTION

1. Plaintiff Edwin Spinks is a resident and citizen of Sangamon County, State of Illinois. On February 24, 2015, Plaintiff underwent a coronary artery bypass grafting procedure at Memorial Medical Center ("MMC") in Springfield, Illinois. During the procedure, the Sorin 3T Heater-Cooler System was used, exposing him to non-tuberculosis Mycobacteria.

2. The Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation, incorporated in England and Wales with headquarters in Milan, Italy. LivaNova is a global medical device company specializing in medical devices used in the treatment of cardiovascular diseases. LivaNova is the party responsible to purchasers in the United States for the Sorin 3T Heater-Cooler Systems.[1]

[1] This information was obtained from the FDA website through the various communications published online regarding the Sorin 3T System. (See Exhibit A)

3. Upon information and belief, the Defendant Sorin Group Deutschland GMBH ("Sorin") is a foreign for-profit corporation, with headquarters in Munich, Germany. Sorin designed, manufactured and marketed the Sorin 3T Heater-Cooler System used in Plaintiffs' surgical procedure in Springfield, Illinois. Plaintiff is under the information and belief that Sorin merged with LivaNova in October, 2015, with LivaNova continuing as the named entity.

4. Upon information and belief, the Defendant Sorin Group USA, Inc. ("Sorin USA") is a United States designer, manufacturer, marketer, and distributor of the Sorin 3T Heater-Cooler System, with its principal place of business in Arvada, Colorado. Plaintiff is under the information and belief that Defendants Sorin and Sorin USA are wholly-owned subsidiaries of LivaNova and market and sell medical devices and products under the name of LivaNova.

JURISDICTION AND VENUE

5. This Court has personal jurisdiction over this action pursuant to FRCP 4 and pursuant to Illinois law. The Defendants are non-domiciliaries of the State of Illinois and contract business within the State of Illinois. The Defendants have committed tortious acts within the State of Illinois, causing injury to a person within the State of Illinois, and said Defendants expect or should reasonably expect to have consequences in the State of Illinois; the Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in the State of Illinois. The Defendants are in the business of researching, designing, developing, testing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third-party related entities, Sorin Group Stockert HeaterCooler 3T thermal regulator devices in the State of Illinois.

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between the parties and the amount in controversy exceeds $75,000.00.

7. Venue is proper in the Central District of Illinois pursuant to 28 U.S.C. §1391(a)(2) because a substantial part of the events or omissions giving rise to the causes of action occurred in Central Illinois and 28 U.S.C. § 1391(c) because Defendants are subject to personal jurisdiction in the Central District of Illinois.

FACTUAL ALLEGATIONS

8. The Plaintiff incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

9. The Defendants market and sell thermal regulator devices to be used on patients in the operating room, including the Sorin 3T Heater-Cooler System ("Sorin 3T System").

10. Prior to February 24, 2015, the Defendants manufactured, introduced, and/or delivered for introduction into interstate commerce, the Sorin 3T System.

11. The Sorin 3T System is intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510K premarket notification process ("510K" or "510K process").[2]

12. Before commercial distribution in the United States of the Sorin 3T System, the Defendants submitted a 510K premarket notification of intent to market the Sorin 3T System with the Secretary of Health and Human Services for FDA approval. The FDA determined that the Sorin 3T System was substantially equivalent to legally marketed predicate devices that do not

[2] A 510K premarket notification is a premarket submission made to the FDA to establish that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (PMA). 21 CFR 807.92(a)(3). See Exhibit B.

require approval of a premarket approval ("PMA") application. This determination was relayed to the Defendants via letter on June 6, 2006, 510K number K052601.[3] Essentially, the 510k process differs from the PMA process in how carefully the FDA examines the safety of the medical device. The PMA process is required for Class III medical devices while Class I and Class II predicate medical devices can be approved through the less rigorous 510K process.

13. The FDA approval allows the Defendants to commercially distribute the Sorin 3T System in accordance with the conditions and regulations described in the approval letter. Any commercial distribution of the Sorin 3T System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act ("the Act"). Generally, the manufacturer must comply with all of the Act's requirements, including but not limited to: "Registration and Listing (21CFR part 807); Labeling (21CFR part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21CFR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act): 21CFR 1000-1050."

14. That on November 4, 2016, MMS sent out letters to patients who had open-heart surgery about a potential infection risk related to this surgery. The letter indicated that The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) were investigating "...a device commonly used to heat and cool blood during open-heart surgery has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as nontuberculous mycobacterium (NTM)."[4]

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[3] Please see the FDA Determination Letter of Approval attached hereto as Exhibit C.

[4] Please see "Exhibit D" attached hereto, which is a copy of the letter submitted to the patients by MMS.

15. *M. chimaera* is a type of nontuberculous mycobacterium (NTM) classified as a slow grower, which can cause serious illness or death[5].

16. *M. chimaera* has been identified in numerous environmental sources, including water. If allowed within the operating field, it poses a significant health risk to surgical patients.[6]

17. Tissue that has been infected with *M. chimaera* can range in possible signs and symptoms including: fatigue, fever, pain, muscle and joint pain, night sweats, weight loss, abdominal pain, nausea, vomiting, and irritation at the surgical sight.[7]

18. Diagnosis of *M. chimaera* can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the infection can be found in the blood from a blood sample. Targeted cultures, screenings, and proper testing are usually not performed unless the physician has been made aware of this type of mycobacterium exposure.

19. While death is certainly a risk of this type of infection, there are treatments available. Those include draining collections of pus or removing the infected tissue, coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time. The type and period of treatment can vary greatly from patient to patient.

20. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System due to the "potential colonization of organisms, including Mycobacteria, in Sorin Heater-Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."[8]

21. The recall instructed all affected customers to follow *new* Instructions for Use, which were outlined in the June 15, 2015 Field Safety Notice Letter for EU English-speaking

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[5] Please see "Exhibit E" attached herein, which is *M.chimaera* infection information.
[6] Id.
[7] Id.
[8] Please see the 07/15/15 Recall Letter attached hereto as Exhibit F.

countries, followed up by a similar letter to users in the United States on August 6, 2015[9], both issued by Christian Peis, the Director of Quality Assurance for Sorin.

22. Sorin indicated that it was providing the Field Safety Notice Letters for the following reasons:

A. [To] remind [affected users] of the importance of following the company's disinfection and maintenance procedures;

B. [To] inform [affected users] that there is a possibility that bacteria can become aerosolized when the heater-cooler device is operated and serve as a source for contamination; and

C. [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.[10]

23. Upon information and belief, the Defendants knew or should have known that design and/or manufacturing defects in its Sorin 3T System made it susceptible to bacterial colonization, specifically Mycobacteria, despite any cleaning and disinfection procedures utilized.

24. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Sorin's Germany and Colorado facilities revealed that the Sorin 3T System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation [were] not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."[11]

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[9] Please see the 6/15/15 Field Safety Notice Letter, attached hereto as "Exhibit G" and 8/6/15 letter.

[10] Id.

[11] Please see the 12/29/15 Warning Letter, attached hereto as "Exhibit H."

25. The FDA noted several other violations by the Defendants in the Warning Letter, which include, but are not limited to, the following:

A. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i);

B. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a);

C. The devices were misbranded in that Sorin failed or refused to furnish material or information respecting the device that is required by or under § 519 of the Act 21 USC § 360i and 21 CFR Part 803 – Medical Device Reporting;

D. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17;

E. Defendants' Sorin 3T System was misbranded due to its failure to notify the agency of its intent to introduce the device into commercial distribution as required by § 510(k) of the Act, 21 USC §360(k); and

F. Failure to notify the agency of significant labeling changes that affected the safety and effectiveness of the device (e.g., distributing the device with modified instructions for use with respect to the operating, maintaining, cleaning, and disinfecting of the device, among other modifications).

26. Contrary to the Defendants' representations and marketing to the FDA, medical community, and to the patients themselves, Defendants' Sorin 3T System has high injury and complication rates, fails to perform as intended, requires patients to undergo additional operations, and has caused severe and sometimes irreversible injuries, conditions, and damages to a significant

number of patients, including Plaintiff, all of which are violations of Federal and Illinois State rules and regulations.

27. In violation of Federal and Illinois State requirements, the Defendants consistently under-reported and withheld information about the propensity of the Sorin 3T System to experience complications and its failure to perform as expected, has misrepresented the efficacy and safety of Defendants' system through various means and media, actively misleading the FDA, the medical community, patients, and the public at large.

28. Defendants knew, and continue to know, that its disclosures to the FDA, the public, and Plaintiff were, and are, incomplete and misleading and that the Sorin 3T System was and is causing numerous patients severe injuries and complications, which violates Federal and State requirements. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, the medical community, health care providers, and patients. As a result, the Defendants actively and intentionally misled the FDA and the public, including the medical community, healthcare providers, and patients, into believing that the Sorin 3T System was safe and effective, leading to the use of Defendants' system during surgical procedures, such as the one undertaken by Plaintiff, as more fully described herein.

29. In violation of Federal and State rules and regulations, the Defendants failed to perform and/or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Sorin 3T System.

30. As compared to similar systems, feasible and suitable alternative designs, procedures, and instructions for use have existed at all times relevant.

31. The Defendants' 3T Sorin System was at all times relevant, utilized in a manner foreseeable to the Defendants.

32. The Defendants provided incomplete, insufficient, and misleading instructions, training, and information to hospitals and physicians, which is in direct violation of Federal and State regulations and in violation of regulations required pursuant to the 510K Approval of the Sorin 3T System in order to increase the number of hospitals and physicians utilizing the device, thereby increasing its sales.

33. The Sorin 3T System used during Plaintiff's surgical procedure was in the same or substantially similar condition as it was when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

34. The injuries, conditions, and complications Plaintiff suffered due to the Sorin 3T System include, but are not limited to, excruciating pain, weakness, excessive additional and debilitating medical treatment, suffering, and permanent injury. Additional information that may be necessary to further establish Plaintiff's claims will be gathered throughout the discovery process of this litigation since Plaintiffs are privy to limited supporting documentation at this time.

35. Despite Defendants' knowledge of the catastrophic injuries, conditions, and complications caused by the Sorin 3T System, in violation of Federal and State requirements, it continued to manufacture, market, provide inadequate instructions for use, and sell the Sorin 3T System, and also failed to adequately warn, label, instruct, and disseminate information with regard to Defendants' Sorin 3T System both prior to and after the marketing and sale of the System.

FACTS SPECIFIC TO THIS CASE

36. Defendants' Sorin 3T System was used during Plaintiff's Coronary Artery Bypass Grafting Procedure, performed at MMS, on or about February 24, 2015, wherein the Plaintiff's surgeon, used the device to assist in the cooling and re-warming of Plaintiff's blood.

37. Over the following days, Plaintiff's condition began to deteriorate. The Plaintiff had a sternal would infection.

38. On or about February 26, 2015, Plaintiff began treatment at MMS for infection in the sternal wound area which appeared to be swollen and contain fluid. Plaintiff was placed on antibiotics. Plaintiff was fitted with a wound vac, and was continued on the antibiotics while the wound contents were cultured. Plaintiff was discharged home with home the wound vac and PICC line, and was scheduled for home health care, as well as regular treatment by his cardiologist and family physician.

39. That shortly after surgery, the Plaintiff began having problems with balance, night sweats, intermittent fevers, and extreme fatigue.

40. That the Plaintiff is currently seeing an infectious disease specialist. He is undergoing blood cultures to determine if he does in fact have a confirmed case of NTM.

COUNT I - NEGLIGENCE

41. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

42. The Defendants owed a duty of reasonable care to the general public, including Plaintiff, when it designed, labeled, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, instructed, and sold the Sorin 3T System, to assure that the product was in compliance with FDA regulations and not defective and/or unreasonably dangerous for its intended purposes and foreseeable uses.

43. The Defendants breached this duty by designing, labeling, manufacturing, assembling, inspecting, testing, marketing, distributing, instructing, and selling the Sorin 3T System in a defective and unreasonably unsafe condition including, but not limited to, its propensity for the colonization of organisms, including Mycobacteria.

44. The Defendants owed Plaintiff a duty of reasonable care to discover defects and/or errors in the machine and to inform and/or warn the FDA and Plaintiff of a defect once it was

discovered. The Defendants violated these duties when they failed to do so, which further placed Plaintiff at risk for harm and injury.

45. The Sorin 3T System differed in design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising from the system that received approval through the 510K process, and thus the design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising of the Sorin 3T System used at GHS during Plaintiff's heart procedure was done so in violation of those requirements.

46. The Defendants had the duty to comply with and not deviate from statutory requirements, which amongst other things, require that the device be manufactured, labeled, and designed according to the standards laid out in the FDA approval. The Defendants violated these duties when it failed to comply therewith and deviated from the statutory requirements.

47. As a direct and proximate result of Defendants' violations, Plaintiff has suffered severe debilitating injuries, economic loss, and other damages, including, but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering.

48. Under Illinois law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of common law negligence.

49. Under Illinois common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in an unreasonably dangerous product proximately causing injuries to the Plaintiff.

COUNT II - STRICT PRODUCTS LIABILITY

50. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

51. Under Illinois 815 ILCS 505/2, the Defendants' sale of the product in a defective condition or unreasonably dangerous condition, along with Defendants' violations of federal regulations as outlined herein, establish a prima facie case of strict liability in tort.

52. As a direct and proximate result of Defendants' violations of Federal and State laws, Plaintiff has suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, and death.

53. Under Illinois common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in an unreasonably dangerous product proximately causing injuries to Plaintiffs.

COUNT III - BREACH OF EXPRESS WARRANTY

54. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

55. The Defendants warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the Sorin 3T System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

56. The Defendants are aware that health care providers and patients, including Plaintiff, rely upon the representations made by the Defendants when choosing, selecting, and purchasing its products, including the Sorin 3T System.

57. Due to the defective and unreasonably dangerous design, labeling, and manufacturing of the Sorin 3T System, which was in violation of statutory requirements and regulations, the product was neither of merchantable quality, nor fit for the ordinary purposes for

which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiff, during foreseeable use.

58. The Defendants' violations of Federal and State statutory rules and regulations and the defective and unreasonably dangerous condition of the Sorin 3T System constituted a breach of the Defendants' express and implied warranties, and such breaches were a direct and proximate cause of the incident and injuries described herein, and for which Plaintiffs are entitled to attorney's fees, compensatory, and punitive damages in an amount to be proven at trial.

COUNT IV - BREACH OF IMPLIED WARRANTIES

59. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

60. Defendants warranted impliedly, through its marketing, advertising, distributors and sales representatives, that the Sorin 3T System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold under 810 ILCS 5/2-314 and 810 ILCS 5/2-315.

61. When the Sorin 3T System was used during Plaintiff's heart procedure, the system was being used for the original purposes for which it was approved and intended.

62. Plaintiff, individually and/or by and through his healthcare provider, relied upon Defendants' implied warranties of merchantability in consenting to have the heart procedure performed with assistance of the Sorin 3T System.

63. Defendants breached these implied warranties of merchantability because the Sorin 3T System was neither merchantable nor suited for the intended uses as warranted.

64. Defendants' breach of its implied warranties resulted in the use of an unreasonably dangerous and defective product during Plaintiff's heart procedure, placing Plaintiff's health and safety in jeopardy.

65. As a direct and proximate result of the Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, the Plaintiff has suffered injury and has further experienced significant mental and physical pain and suffering, sustained permanent injury, underwent rigorous and debilitating medical treatment, suffered financial and/or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income and other damages, for which Plaintiff is entitled plus costs of suit.

COUNT V - NEGLIGENT MISREPRESENTATION

66. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

67. The Defendants negligently misrepresented to the FDA, the medical community, Plaintiff, and the public, the defective nature and extent of adverse reactions and labeling errors of the Sorin 3T System.

68. The Defendants failed to adhere to FDA regulations by failing to appropriately report all of the information and knowledge in their possession in regards to the dangers that the Defendants knew their product presented, including, but not limited to, the fact that colonization of Mycobacteria inside the Sorin 3T System could occur if specific disinfection and maintenance procedures were not implemented.

69. Had the Defendants accurately and truthfully represented to the FDA, the medical community, Plaintiff, and the public, the material facts relating to the risks of the Sorin 3T System, Plaintiff and/or Plaintiff's healthcare provider would not have utilized the Sorin 3T System as it did during Plaintiff's heart procedure.

70. Under Illinois law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of negligent misrepresentation.

71. Under Illinois common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in the negligent misrepresentation of an unreasonably dangerous product proximately causing injuries to Plaintiff.

72. As a direct and proximate result of the Defendants' negligent misrepresentations and violations as outlined above, Plaintiff has suffered injuries and have further experienced significant mental and physical pain and suffering, sustained permanent injury, underwent rigorous and debilitating medical treatment, suffered financial and/or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income and other damages, for which Plaintiff is entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VI - MISREPRESENTATION BY OMISSION

73. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

74. Throughout the relevant time period, Defendants knew that the Sorin 3T System was defective and unreasonably unsafe for intended purposes, which the Defendants failed to properly report to the FDA.

75. The Defendants were under a duty to disclose to the FDA, Plaintiff, and the medical community, the defective nature and extent of adverse reactions and labeling errors of the system because the Defendants were in a superior position to know the true quality, safety, and efficacy of the Sorin 3T System.

76. The Defendants concealed from and/or failed to disclose to the FDA, Plaintiff, Plaintiff's healthcare providers, and the medical community that its Sorin 3T System was defective, unsafe, and unfit for the purposes intended, and that it was not of merchantable quality.

77. The facts concealed and/or not disclosed to the FDA, Plaintiff, or the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize the Sorin 3T System, and were facts that were required to be disclosed pursuant to Federal and State statutes and regulations.

78. Under Illinois law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of misrepresentation by omission.

79. Under Illinois common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant thereto, which resulted in Defendants' misrepresentation by omission of an unreasonably dangerous product that proximately caused injuries to the Plaintiff.

80. As a direct and proximate result of the Defendants' concealment and misrepresentations by omission and violations outlined above, the Plaintiff has suffered severe injuries and have further experienced significant mental and physical pain and suffering, sustained permanent injury, underwent rigorous and debilitating medical treatment, suffered financial and/or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income and other damages, for which Plaintiff is entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VII - VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICE ACT

81. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

82. At all times, relevant to this action, the Illinois Consumer Fraud and Deceptive Business Practice Act, codified at 815 ILCS 505/1 et.seq. The section states:

a Unfair methods of competition and unfair or deceptive acts or practices including but not limited to the use or employment of any deception, fraud, false, pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby.

83. The Defendants have engaged in deceptive acts or practices in violation of the Illinois Consumer Fraud and Deceptive Business Practice Act, including but not limited to, utilizing deception, fraud, misrepresentation, concealment, omission, and suppression of research from investigations, adverse events reported to the FDA, and clinical trials regarding the safety, efficacy, instructions for use, and the unreasonably dangerous nature of the Sorin 3T System.

84. The Defendants violated the Illinois Consumer Fraud and Deceptive Business Practice Act by concealing, omitting, and failing to inform the FDA, the Plaintiffs, the medical community, and other purchasers of the failures, adverse reactions, complications, and the insufficiency of the Instructions for Use as it related to the Sorin 3T System.

85. Defendants' deceptive acts and practices occurred during a course of conduct involving trade or commerce.

86. As a direct and proximate cause of the Defendants' violations of Federal requirements and the Illinois Consumer Fraud and Deceptive Business Practice Act, Plaintiff has

sustained severe physical and emotional injuries and economic loss, for which Plaintiff is entitled compensatory damages in an amount to be proven at trial.

ACTUAL DAMAGES

87. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

88. As a direct and proximate result of the acts, omissions, and violations of the Defendants alleged herein, Plaintiffs suffered injuries and damages. The injuries and damages for which Plaintiffs seek compensation from the Defendants include, but are not limited to:

a physical pain and suffering of a past, present and future nature;

b emotional pain and suffering of a past, present and future nature;

c permanent impairment and scarring;

d medical bills and expenses of a past, present and future nature;

e loss of earnings;

f loss of earning capacity;

g loss of enjoyment of life;

h any and all such further relief, both general and specific, to which they may be entitled to under the premises.

PRAYERS FOR RELIEF

89. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation in this Complaint.

90. **WHEREFORE, PREMISES CONSIDERED,** the Plaintiff brings this Complaint against the Defendants for personal injuries and pray for a judgment against the Defendants for compensatory and punitive damages, in an amount considered fair and reasonable by a jury and for all such further relief, both general and specific, to which Plaintiff may be entitled under the premises.

Respectfully submitted,

Geisler Law Offices

By: _____

Gary F. Geisler
ARDC No. 0930350
241 S. Main Street
Decatur, Illinois 62523
Telephone: (217) 423-8081
Facsimile: (217) 423-8221

JURY REQUEST

The Plaintiff hereby respectfully requests a trial by jury.

By: _____

Gary F. Geisler
ARDC No. 0930350
241 S. Main Street
Decatur, Illinois 62523
Telephone: (217) 423-8081
Facsimile: (217) 423-8221

Rule 11 Certification

Pursuant to Rule 11 of the Federal Rules of Civil Procedure, the undersigned does hereby certify and represent that he is an Attorney at Law licensed by the State of Illinois and to appear before the district courts of the Central District of Illinois and that he has made a reasonable investigation of the facts herein, and has determined that there is a good faith basis for the bringing of this action under existing law or the establishment of new law, that the allegations and other factual contentions have evidentiary support and that it is not being presented for an improper purpose.

February 15, 2017

Gary F. Geisler
ARDC No. 0930350
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Telephone: (217) 423-8081
Facsimile: (217) 423-8221

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

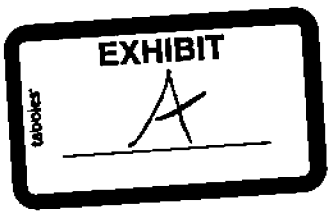
Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Principal Consultant, Regulatory Services
49 Plain Street
North Attleboro, MA 02760

Re: K052601
Stockert Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary Bypass Temperature Controller
Regulatory Class: Class II
Product Code: DWC
Dated: May 15, 2006
Received: May 16, 2006

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUN - 6 2006

K052601

Traditional 510(k) Premarket Notification
510(k) Summary
Sorin Group Deutschland GmbH, Stöckert Heater-Cooler System 3T

1. SUBMITTER/HOLDER

Sorin Group Deutschland GmbH
Lindberghstrasse 25
80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010

Date Prepared: September 19, 2005

2. DEVICE NAME

Proprietary Name: Stöckert Heater-Cooler System 3T
Common/Usual Name: Heater-Cooler
Classification Name: Cardiopulmonary bypass temperature controller

3. PREDICATE DEVICE

- Cincinnati Subzero Hemotherm (CSZ Hemotherm) (K811742)
- Alpha Omega, Inc. Dual² Cooler-Heater (K001520)
- Jostra AB Heater-Cooler Unit 30 (K031544)

4. DEVICE DESCRIPTION

The Sorin Group Deutschland GmbH Stöckert Heater-Cooler System 3T consists of standard and optional components. The standard components comprise the heater-cooler base unit, water connectors, CAN-connecting cable for the S3 System, potential equalization cable, and Operating Instructions. Patient blankets used with the System are already legally marketed in the United States.

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5. INTENDED USE

The Stöckert Heater-Cooler System 3T is intended to provide temperature-controlled water to heat exchanger devices (cardiopulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Sorin Group Deutschland GmbH bases the claim of substantial equivalence of the Stöckert Heater-Cooler System 3T to the cited predicate devices based on equivalence in intended use, fundamental technological and operational characteristics. Testing submitted in this premarket notification demonstrates that the Stöckert Heater-Cooler System 3T complies with specifications, meets user requirements, and the differences between the proposed device and cited predicate devices do not raise new issues of safety or effectiveness.

Indications for Use

510(k) Number: K052601

Device Name: Stöckert Heater-Cooler System 3T

Indications for Use:

The Stöckert Heater-Cooler System 3T is used with a Stöckert S3 heart-lung machine and/or any other heart lung machine featuring a separate temperature control for extracorporeal perfusion of durations of up to 6 hours.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052601

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Memorial MEDICAL CENTER
701 North First Street • Springfield, Illinois 62781-0001
www.memorialmedical.com • **Phone (217) 788-3000**
A Memorial Health System Affiliate

November 4, 2016

Edwin W. Spinks
6523 Brent Dr
Springfield, IL 62712-7523

Dear Patient:

Memorial Medical Center is notifying patients who had open-heart surgery about a potential infection risk related to this surgery. You have been identified in clinical records as a patient who had open-heart surgery during the timeframe associated with this risk.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are investigating reports that a device commonly used to heat and cool blood during open-heart surgery has been linked to a rare bacterial infection caused by *Mycobacterium chimaera,* a type of bacteria known as nontuberculous mycobacterium (NTM). Due to this risk, the CDC has issued a national alert with guidelines regarding this device, which is used in 60 percent of open-heart surgeries worldwide. For patients who have had one of these surgeries, the chances of getting this infection are very low. CDC estimates the risk to be less than 1 percent. To date, MMC has not had any patients with this rare bacterial infection; in addition, there are no reported cases in Illinois. This infection grows very slowly and may be difficult to diagnose. It is possible to develop symptoms years after surgery, so it is important to know the symptoms.

Symptoms of an NTM infection include:

- night sweats
- muscle aches
- weight loss
- fatigue
- unexplained fever

Discuss any symptoms or questions you may have with your primary care physician. This infection cannot be spread person to person.

We understand that you and your family might have additional questions or concerns about this information. To help answer your questions, we have established a hotline at 217-588-3727.

Sincerely,

Rajesh Govindaiah M.D.

Rajesh G. Govindaiah, MD
Senior Vice President & Chief Medical Officer
217-788-3527

VHA.

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United States
Environmental Protection
Agency

Office of Science and Technology
Office Of Water
Washington DC, 20460

EPA-822-F-02-002
March 2002

EPA MYCOBACTERIA: DRINKING WATER FACT SHEET

GENERAL INFORMATION

- *Mycobacteria* belong to the
  - Order Actinomycetales,
  - Family Mycobacteriaceae, and
  - Genus Mycobacterium.

- There are approximately 90 recognized species of *Mycobacteria*, over 20 of which are known to cause disease in humans.

- Non-tuberculosis mycobacteria (NTM) have been identified in numerous environmental sources, including water.

- There has been recent interest in the NTM species, due to their ability to cause disease in humans and animals after environmental exposures.

Characteristics and Classification:

- *Mycobacteria* are rod-shaped bacteria which require oxygen for growth. Each species has an acid-fast staining property during some stage of its growth cycle.

- Mycobacterium have been referred to as the 'ducks of the microbial world' due to their thick, waxy, outer coating which enables them to thrive in aquatic environments.

- The various species of Mycobacteria are classified based on their growth rates in culture into the following three categories: slow growers, rapid growers and those not yet cultivated.

ENVIRONMENTAL OCCURRENCE

- NTM have been found to be ubiquitous in the environment.

- NTM species have been isolated from numerous water sources, including waste water, surface water, recreational water, ground water and tap water.

- Piped water supplies are readily colonized by mycobacteria. Biofilms may serve as a reservoir for these opportunistic pathogens.

- Few studies are available which quantify the concentrations of NTM in water. Some reports indicate that NTM have been recovered in 11% to 38% of raw water samples at concentrations of <0.1 to 48 organisms per milliliter of water.

HEALTH EFFECTS IN HUMANS

Transmission to Humans:

- NTM are not thought to be transmitted by the human to human route, but are instead thought to be transmitted from environmental sources.

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- Exposure pathways of potential concern include ingestion, inhalation and entry of organisms through abraded skin.

Symptoms:

- The clinical symptoms seen following infection with NTM depend greatly on the mycobacterial species.

- Common clinical syndromes include:
  - Pulmonary infection
  - Infection of the lymph nodes
  - Ear infection
  - Skin & soft tissue infection
  - Catheter-associated infection
  - Whole Body (e.g., blood) ifection

- In general, symptoms seen in children are similar to those reported in adults. Pulmonary disease is relatively rare in children. The most common form of clinically significant NTM infection in children is infection of the lymph nodes in the neck.

Treatment:

- Treatment of NTM infection depends on the location and extent of disease involvement, status of the host's immune system, and the mycobacterial species.
  - Treatment of pulmonary and whole body infections most often requires a multidrug regimen.
  - Treatment for cutaneous lesions may include surgical removal or drug therapy. Often, cutaneous lesions will disappear without requiring treatment.

Disease Occurrence and Outbreaks:

- NTM diseases are not reportable, therefore, information regarding the occurrence of disease outbreaks is likely to be underestimated. However, human infections due to NTM appear to be increasing at a significant rate across the United States.

- CDC estimates that NTM diseases (non-AIDS related) occur in 1.8 out of 100,000 individuals per year in the U.S., of which approximately 72% are attributable to *M. avium* complex (MAC).

- It has been estimated that in the U.S., 25% to 50% of individuals with AIDS will develop NTM diseases, primarily attributable to MAC. The recent use of highly active anti-retro viral therapy (HAART) in AIDS patients suggests a decrease in the risk and rate of NTM infections in these individuals.

- Waterborne NTM have been associated with hospital (nosocomial) outbreaks worldwide. These disease outbreaks usually involve sternal wound infections, plastic surgery wound infections or postinjection abscesses. Mycobacterial infections in patients undergoing dialysis treatment have also been reported.

- Although not reported frequently, some outbreaks of mycobacterial infection have been reported after exposures in public swimming areas.

- Some false outbreaks have been reported as a result of contaminated sampling equipment or water supplies used for diagnostic procedures. Therefore, it is important that precautions be taken when performing diagnostic tests in order to lessen the chance of false-positive test results.

HEALTH EFFECTS IN ANIMALS

- Several of the NTM species are known to cause disease in animals. These include MAC, *M. marinum*, *M. ulcerans*, *M. paratuberculosis*, *M. simiae*, *M. fortuitum* and *M. smegmatis*.
- Symptoms seen following infection depend on the host organism and the species of NTM.
- *M. paratuberculosis* is the causative agent of Johne's disease; a slow, progressive infection of the intestine which occur mainly in cattle, sheep and goats.
- *M. marinum* is an important cause of death and economic loss in fish populations.
- *M. fortuitum* and *M. smegmatis* are known to produce mastitis in sheep and cattle and skin and soft tissue disease in domestic house cats.
- Destruction or isolation of infected animals is the most common form of treatment, however, drug therapy has been successful in some cases.

RISK FACTORS

- The general population (healthy individuals) is fairly resistant to infection.
- Certain individuals are at increased risk for developing NTM associated diseases due to the presence of predisposing factors, including:
  - traumatic breaches of the skin
  - pre-existing pulmonary disease or damage
  - lung architectural defects
  - bronchiectasis
  - generalized congenital and acquired immunosuppressive disorders (e.g., HIV)

ANALYTICAL METHODS

- The most common method for the identification of mycobacterial species in water samples is through culture isolation. The bacterial culture is evaluated for morphology, growth rates and other biochemical parameters in order to determine the species.
- Several other methods have been developed for the detection of mycobacteria in samples, including:
  - Polymerase chain reaction (PCR)
  - Radiometric methods (BACTEC)
  - GC/MS
  - Nucleic acid probes
- Although promising, these methods only provide qualitative information regarding the presence of mycobacteria in water and do not provide a measure of concentration.
- When collecting samples for use in culture isolation, a decontamination step is necessary to kill the other bacteria and fungi present in the water. This is because there is a large problem of contamination of samples due to the presence of non-mycobacterial bacteria which are capable of growing at faster rates than the species of interest. Acids, alkalis and detergents are often used during the decontamination process since mycobacteria are generally more resistant to these chemicals than are other bacteria.

WATER TREATMENT

- In general, two mechanisms can be used to eliminate microbes from drinking water: removal or disinfection.
- Removal treatments such as filtration, sedimentation, coagulation, flocculation and adsorption are primarily physical operations that remove bacteria from the water.
- Disinfection treatment technologies may kill bacteria using chemicals such as chlorine, ozone, bromine, iodine or hydrogen peroxide which are added to the water, or may inactivate microbes via UV radiation.
- NTM are relatively resistant to standard water disinfection procedures and, therefore, can occur in potable water.
- Overall, there is little information available regarding the effectiveness of various disinfection treatments on mycobacterial species in water. However, EPA is actively studying methods to reduce the occurrence of *Mycobacteria* in drinking water and will update this fact sheet when better information becomes available.

REGULATORY INFORMATION

- EPA has established a Maximum Contaminant Level Goal (MCLG) of zero organisms (bacteria and viruses), including mycobacteria, for drinking water. An MCLG is a non-enforceable guideline based solely on an evaluation of possible health risks, taking into consideration a margin for public safety.

ADDITIONAL INFORMATION

- EPA has established the Safe Drinking Water Hotline, a toll-free number for further information on drinking water quality, treatment technologies, and for obtaining Health Advisories or other regulatory information.
- Safe Drinking Water Hotline:
  800-426-4791
  9:00 a.m. - 5:30 p.m. (Eastern Time)
  Monday-Friday (excluding holidays). Your state or county health officials or experts in your state's Department of Environmental Protection or Natural Resources may also be of assistance.

UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA Safety Communication

The FDA is updating its June 1, 2016 **Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm)** to provide new information about *Mycobacterium chimaera* (*M. chimaera*) infections associated with the use of the 3T in U.S. patients who have undergone cardiothoracic surgeries. This communication also contains updated recommendations to help prevent the spread of infection related to the use of these devices.

October 13, 2016

Audiences:

- Health care providers who use 3T Heater-Cooler System
- Primary care providers who are responsible for the ongoing care of patients who have undergone cardiothoracic surgery
- Patients who have undergone cardiothoracic surgery
- Hospital staff who are responsible for operating and maintaining 3T Heater-Cooler System
- Health care facilities that perform procedures using the 3T Heater-Cooler System

Medical Specialties: Cardiothoracic Surgeons, Cardiovascular Surgeons, Orthopedic Surgeons, Neurosurgeons, General Surgeons, Anesthesiologists, Infection Control, Infectious Disease Physicians, Pediatrics, Primary Care, and Intensive Care Physicians

Product: The Stöckert 3T Heater-Cooler System (3T), manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), is intended to provide temperature-controlled water to 1) oxygenator heat exchangers, 2) cardioplegia (paralysis of the heart) heat exchangers, and/or 3) warming/cooling blankets to warm or cool a patient during cardiopulmonary bypass procedures lasting six hours or less.

Purpose: The FDA is updating its June 1, 2016 **Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm)** to provide new information about *Mycobacterium chimaera* (*M. chimaera*) infections associated with the use of the 3T in U.S. patients who have undergone cardiothoracic surgeries. This communication also contains updated recommendations to help prevent the spread of infection related to the use of these devices.

As the FDA continues to investigate infections associated with the 3T, we believe health care facilities should take additional steps to help mitigate the risk of infection associated with the use of these devices

Summary of Problem and Scope:

Heater-cooler devices (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/) are commonly used during cardiothoracic surgeries, as well as other medical and surgical procedures, to warm or cool a patient in order to optimize medical care and improve patient outcomes. Heater-cooler devices have water tanks that provide temperature-controlled water to external heat exchangers or warming/cooling blankets through closed circuits. Although the water in the circuits does not come into direct contact with the patient, there is the potential for contaminated water to enter other parts of the device and aerosolize, transmitting bacteria through the air and through the device's exhaust vent into the environment and to the patient. In October 2015, the FDA issued a **Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm)** to provide recommendations to help minimize patient risk of infections associated with heater-cooler devices. Since issuing that communication, the FDA has continued to evaluate the causes and risk factors for transmission of microbial agents associated with heater-cooler devices and has collaborated with professional societies, public health partners, and experts to develop strategies to minimize patient exposure.

A European study[1] published in April 2016 describes a link between *M. chimaera* clinical samples from several European infected cardiothoracic patients, samples from the heater-cooler devices used during these patient's procedures, and environmental samples from the device manufacturer's production and servicing facility in Germany. The results of this paper suggest a direct link between the *M. chimaera* that infected European patients during open-chest cardiac surgery, and the *M. chimaera* isolated from the 3T heater-cooler model utilized during these patients' surgeries.

M. chimaera is a type of nontuberculous mycobacterium (NTM) classified as a slow grower. *M. chimaera* may cause serious illness or death. The FDA believes *M. chimaera* infections associated with the 3T are rare. However, they are difficult to detect because infected patients may not develop symptoms or signs of infection for months to years after initial exposure.

On June 1, 2016, the FDA issued a **Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm)** specific to *M. chimaera* infections associated with the use of the 3T. Testing conducted by the manufacturer in August 2014 found *M. chimaera* contamination on the production line and water supply at the 3T manufacturing facility. The 3T devices manufactured at this facility were distributed worldwide. In response to the *M. chimaera* findings in August 2014, the manufacturer added cleaning and disinfection procedures to the production line in September 2014. Samples taken at the same manufacturing facility, by the German Regulatory Authorities in July 2015 did not show *M. chimaera*, potentially indicating the contamination at the manufacturing facility had been resolved. Although the manufacturer of 3T devices added cleaning and disinfection procedures to the production line in September 2014, the FDA is now aware of some 3T devices manufactured after September 2014 which have tested positive for *M. chimaera.* It has not been confirmed whether these devices were contaminated at the manufacturing facility or became contaminated at the user facility. To date, the FDA is not aware of *M. chimaera* patient infections associated with 3T devices that were manufactured after September 2014.

The June 1, 2016 **Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm)** also stated the FDA received reports of U.S. patients infected with *M. chimaera* after undergoing cardiothoracic surgery that involved use of the 3T devices. Each of those reports related to 3T devices that were manufactured prior to September 2014. The Centers for Disease Control and Prevention (CDC) in conjunction with National Jewish Health has **performed (https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w)** whole genome sequencing on clinical isolates from infected patients and samples taken from the 3T devices from hospitals

representing geographically distinct regions within the U.S. (Pennsylvania and Iowa) where clusters of patient infections with *M. chimaera* were identified. Each of the isolates tested were associated with devices manufactured before September 2014. Samples of the water drained from the 3T devices and air samples collected while the devices were in operation were also tested. The results obtained strongly suggest that the tested 3T devices had a common source of *M. chimaera* contamination. Sequence comparisons between U.S. and European Union (EU) samples, as well as samples from the manufacturing site, would provide additional information in evaluating the potential for point source contamination at the production site. However, EU sequencing results have not been shared to date.

As new information becomes available, the FDA will evaluate the information and update its recommendations, as appropriate.

UPDATED Recommendations for Health Care Facilities and Staff:

If your facility uses 3T devices, you should:

- **Immediately remove from service any heater-cooler devices, accessories, tubing, and connectors that have tested positive for *M. chimaera* or have been associated with known *M. chimaera* patient infections at your facility.**
- **Use new accessories, tubing, and connectors to prevent recontamination when using a different heater-cooler device.**
- **Direct and channel the heater-cooler exhaust away from the patient, e.g., to the operating room exhaust vent.**
- **Be aware that device contamination also may occur from other sources such as environmental contamination or device contact with contaminated accessories.**
- **Review the recommendations in CDC's Health Advisory (https://emergency.cdc.gov/han/han00397.asp)**
- **Be aware that heater-cooler devices are important in patient care. In appropriately selected patients, the benefits of temperature control during open chest cardiothoracic procedures generally outweigh the risk of infection transmission associated with the use of these devices.**

If your facility has 3T devices manufactured prior to September 2014, you should:

- **Strongly consider transitioning away from the use of these devices for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risks of patient infection.**
  - **Use of these devices should be limited to emergent and/or life-threatening situations if no other heater cooler devices are available.**
  - **Follow the FDA's earlier recommendations to help mitigate the risks of patient infection.**
  - **Be aware that testing of heater-cooler devices to identify units contaminated with *M. chimaera* presents technical challenges related to sample collection, the long culture time, and the high rate of false negative tests. Therefore, it is not recommended at this time.**

If your facility has 3T devices manufactured after September 2014, you should:

- **Follow the FDA's earlier recommendations to help mitigate the risks of patient infection.**
- **Be aware that testing of heater-cooler devices to identify units contaminated with *M. chimaera* presents technical challenges related to sample collection, the long culture time, and the high rate of false negative tests. Therefore, it is not recommended at this time.**

The FDA recommends facilities and staff using heater-cooler units CONTINUE to implement the following measures to help reduce risk to patients:

- Strictly adhere to the cleaning and disinfection instructions provided in the manufacturer's device labeling. Ensure you have the most current version of the manufacturers' instructions for use readily available to promote adherence.
- Do not use tap water to rinse, fill, refill or top-off water tanks since this may introduce NTM organisms. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. When making ice needed for patient cooling during surgical procedures use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Deionized water and sterile water created through reverse osmosis is not recommended because it may promote corrosion of the metal components of the system.
- Direct the heater-cooler's vent exhaust away from the surgical field to mitigate the risk of aerosolizing heater-cooler tank water into the sterile field and exposing the patient.
- Establish regular cleaning, disinfection and maintenance schedules for heater-cooler devices according to the manufacturers' instructions to minimize the risk of bacterial growth and subsequent patient infection.
- Develop and follow a comprehensive quality control program for maintenance, cleaning, and disinfection of heater-cooler devices. Your program may include written procedures for monitoring adherence to the program and documenting set up, cleaning, and disinfection processes before and after use.
- Immediately remove from service heater-cooler devices that show discoloration or cloudiness in the fluid lines/circuits, which may indicate bacterial growth. Consult your hospital infection control officials to perform the appropriate follow up measures and report events of device contamination to the manufacturer and to the FDA **via MedWatch (/Safety/MedWatch/HowToReport/ucm2007306.htm)**.
- Consider performing environmental, air, and water sampling and monitoring if heater-cooler contamination is suspected. Environmental monitoring requires specialized expertise and equipment to collect and process samples, which may not be feasible in all facilities.
- Health care facilities should follow their internal procedures for notifying and culturing patients if they suspect infection associated with heater-cooler devices.
- Submit a report to the manufacturer and to the FDA **via MedWatch (/Safety/MedWatch/HowToReport/ucm2007306.htm)**, if you suspect heater-cooler devices have been associated with patient infections.

Recommendations for Patients:

- Be aware that:
  - in the U.S., most cardiopulmonary bypass procedures involve the use of a heater-cooler device.
  - heater-cooler devices are important in patient care and, in appropriately selected patients, the benefits of temperature control necessary during open chest cardiothoracic proceduresgenerally outweigh the risk of infection transmission associated with using these devices.
  - the FDA has received reports of patient infections associated with exposure to *M. chimaera* when contaminated 3T heater-cooler device were used during surgery.
  - *M. chimaera* infections are difficult to detect because infected patients may not develop symptoms or signs of infection for months to years after initial exposure.
  - there may be an increased risk of infection if you received a heart valve, graft, left ventricular assist device (LVAD), or any other prosthetic product/material or had a heart transplant.

- If you have undergone cardiopulmonary bypass, be aware of the possible signs and symptoms of NTM infection. These may include:
  - fatigue
  - fever
  - pain
  - redness, heat, or pus at the surgical site
  - muscle pain
  - joint pain
  - night sweats
  - weight loss
  - abdominal pain
  - nausea
  - vomiting
- If you have undergone a cardiopulmonary bypass procedure and are experiencing any of the signs and symptoms of NTM infection as outlined above, contact your health care provider as soon as possible.
- If you are not currently experiencing any changes in your general health, inform your health care provider during your next wellness visit that you have undergone a cardiopulmonary bypass procedure to determine if you require further testing or monitoring for possible exposure to NTM.

Additional information for patients is available on FDA's Heater-Cooler Devices "**Information for Patients (/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492585.htm)**" webpage.

FDA Activities:

On December 29, 2015, the FDA issued a **Warning Letter (/ICECI/EnforcementActions/WarningLetters/2015/ucm479684.htm)** to LivaNova PLC (formerly Sorin Group Deutschland GmbH) for its Stöckert 3T Heater-Cooler System after inspections conducted at facilities in Munchen, Germany and Arvada, Colorado revealed significant issues, including quality system and premarket clearance violations. Given the serious nature of the violations, the 3T devices manufactured by the Munchen facility are subject to import alert. This restricts the availability of the 3T devices to only those facilities that determine use of the device is medically necessary.

Sorin Group Deutschland GmbH initiated an ongoing corrective action for the 3T in July 2015, and has included updates to instructions for use with new cleaning instructions and instructions for determining if a device is contaminated with biofilm or NTM. Further updates to this recall are expected and will be evaluated by the FDA for their ability to further reduce infection risk. Please see **the FDA medical device recall database entry (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&knumber=K052601)** for more information regarding corrective actions by the manufacturer.

In June 2016, the FDA **convened (/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm485091.htm)** the Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting and received expert clinical opinion and recommendations for patient notification and patient follow-up procedures. The panel also discussed **recommendations**

(/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM505732.pdf) for sampling and monitoring of the 3T and other heater-cooler devices, including regular visual monitoring of contamination within the water circuit, replacement of accessories (e.g. tubing) on a regular basis, and testing for water quality to assure adequate disinfection procedures are being performed. These recommendations are included in this Safety Communication.

The FDA continues to be actively engaged with the manufacturer, health care facilities and the CDC in evaluating risk and mitigation measures and will provide updates, as appropriate, as new information becomes available.

Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**. Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the use of medical devices. Health care providers should submit voluntary reports of infection transmission associated with heater-cooler devices or reports describing difficulty following the manufacturers' instructions for use to the agency via the **Medical Device Reporting (MDR) (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** process. If a health care provider suspects bacterial contamination of the heater-cooler device following use, we encourage the health care provider to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**.

Additional Resources:

- **FDA Communications on Heater-Cooler Devices**
  - **Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Stöckert 3T Heater-Cooler System: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm)** (June 1, 2016) - ARCHIVED
  - **Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm)** (October 15, 2015)
    Heater-Cooler Informational Webpage (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm)
- **From the Centers for Disease Control and Prevention (CDC)**
  - Perkins KM, Lawsin A, Hasan N, et al. ***Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States (https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w)***. MMWR Morb Mortal Wkly Rep 2016;65:1117–1118. DOI
    https://emergency.cdc.gov/han/han00397.asp (https://emergency.cdc.gov/han/han00397.asp)
  - **CDC Health Advisory: CDC Advises Hospitals to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used during Cardiac Surgery (https://emergency.cdc.gov/han/han00397.asp)** (October 13, 2016)
  - **Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units (http://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-**

Class 2 Device Recall STOCKERT HEATERCOOLER SYSTEM 3T

See Related Information[22]

Date Posted	July 15, 2015
Recall Status[1]	Open
Recall Number	Z-2080-2015
Recall Event ID	71593[23]
510(K)Number	K052601[24]
Product Classification	Controller, temperature, cardiopulmonary bypass[25] - **Product Code** DWC[26]
Product	Sorin Stockert Heater-Cooler 3T, 120 V / 60 Hz Temperature control for extracorporeal perfusion of durations up to 6 hours.
Code Information	Product code 16-02-85 Serial number 16S10958-16S15634
Recalling Firm/ Manufacturer	Sorin Group USA, Inc. 14401 W 65th Way Arvada CO 80004-3503
For Additional Information Contact	Cheri Voorhees 303-467-6306
Manufacturer Reason for Recall	Potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per Instructions for Use.
FDA Determined Cause [2]	Error in labeling
Action	Sorin Group issued a Field Safety Notice dated June 15, 2015, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to review their inventory and identify any affected devices. For each unit customers were instructed to determine if the device has been maintained according to the Instructions for Use. If yes, customers should strictly adhere to the new Instructions for Use. Customers were also provide with a Response form to confirm they received, read and understood the Field Notice. Customers were instructed to return the completed form to assist in monitoring the effectiveness of the communication. For technical support customers should call 1-800-221-7943, ext 6355. For questions regarding this recall call 303-467-6306.
Quantity in Commerce	1755
Distribution	Worldwide Distribution - US (nationwide) and Internationally to AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SK, AE, AR, AU, AZ, BD, BH, BR, BY, CA, CL, CN, CO, CR, DZ, EC, EG, ET, GE, GY, HK, ID, IL, IN, IQ, IR, JO, JP, KR, KW, KZ, LB, LK, LY, MA, MN, MU, MX, MY, NG, NP, NZ, OM, PA, PE, PH, PK, PR, PS, QA, RE, RU, SA, SG, SV, SY, TH, TN, TR, TT, TW,

EXHIBIT F

UA, VN, ZA.

Total Product Life Cycle TPLC Device Report[27]

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[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = DWC and Original Applicant = SORIN GROUP DEUTSCHLAND GMBH[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
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11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=71593
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K052601
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DWC
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DWC
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DWC
28. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DWC&knumber=&applicant=SORIN%20GROUP%20DEUTSCHLAND%20GMBH

Page Last Updated: 06/13/2016

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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10903 New Hampshire Avenue
Silver Spring, MD 20993
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U.S. Department of Health & Human Services

Links on this page:

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

August 6, 2015

Customer Name
Address
City, State Zip

Subject: Update to the Field Safety Notice for Heater-Cooler System 3T

Dear Valued Customer:

You recently received a Field Safety Notice from Sorin Group regarding the Heater-Cooler System 3T (Reference # 9611109-06/03/15-002-C, dated June 15, 2015).

The purpose of this Field Safety Notice was to:

- Remind you of the importance of following disinfection and maintenance procedures.
- Inform you that if your Heater-Cooler 3T is not properly maintained and it becomes contaminated, there is a possibility that bacteria can be aerosolized when the device is operated serving as a potential source for contamination.
- Provide you with updated instructions for use regarding disinfection and maintenance procedures.

This letter is to inform you that the Heater-Cooler System 3T Operating Instructions provided with the Field Safety Notice dated June 15, 2015 were intended for distribution to English speaking countries in the European Union (EU) rather than for the United States.

Although the EU and USA cleaning and disinfection procedures are equivalent, the EU procedure includes additional chemicals only available in other countries. Additionally, the USA Operating Instructions include information specific to the U.S. such as English units of measure and an indications for Use statement.

The USA Heater-Cooler System 3T Operating Instructions are attached to this letter.

For your convenience, the USA Heater-Cooler System 3T Operating Instructions are available on the Sorin Group website at www.sorin.com/3t . They can be viewed, saved or printed as you prefer.

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Steuer-Nummer: 143/181/70429

EXHIBIT
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Customer Actions:

- Please discard all existing Heater-Cooler System 3T Operating Instructions and replace them with the attached USA Heater-Cooler System 3T Operating Instructions.
  Note: The current USA Heater-Cooler System 3T Operating Instructions are CP_IFU_16-XX-XX_USA_014. This identification number is printed at the bottom of each page.
- Follow the actions detailed in the Heater-Cooler System 3T Field Safety Notice dated June 15, 2015.
- Please complete and return the attached Customer Response Form by fax to 303-467-6502 or by email to USFSN@sorin.com.

Contact Information:

Please contact your Sorin Group account representative if you have any questions. If further assistance is required, please contact:

Technical Services hotline at 1-800-221-7943, extension 6355

For your reference, we have also created a list of Frequently Asked Questions, Quick Start Instructions and a 3T Disinfection Video on our website at www.sorin.com/3t .

Sorin Group is committed to providing quality products and services. Thank you for your cooperation in this matter. This information will also be provided to the FDA.

Sincerely,

Christian Peis
Director Quality Assurance

Attachment 1: Affected Products List

Attachment 2: Customer Response Form

Attachment 3: USA Heater-Cooler System 3T Operating Instructions

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

ATTACHMENT 1

Affected Product List

UPDATE TO THE FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385

Please note, all Sorin Heater-Cooler System 3T Devices are affected. Refer to the Customer Response Form for your affected products.

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ATTACHMENT 2

Customer Response Form

UPDATE TO THE FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C
Including USA Heater-Cooler 3T System Operating Instructions

According to our records you have the following affected products:

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form: By fax to 303-467-6502 or by email to USFSN@sorin.com.

Section 1 - Please Complete this section:

We HAVE reviewed and understand this Field Safety Notice ☐ Yes ☐ No

WE HAVE implemented the proper Operating Instructions ☐ Yes ☐ No

Customer Name: _____
Contact Name: _____
E-mail: _____
Fax No.: _____
Phone Number: _____

Submitted by .....

Signature ..... Date ...../...../.....

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ATTACHMENT 3

USA Heater-Cooler System 3T Operating Instructions

UPDATE TO THE FIELD SAFETY NOTICE

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SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

«Name1»
«Name2»
«Name3»
«Address»
«Address»

FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices

Affected Devices:	Sorin Group perfusion system – Heater Cooler 1T and Heater Cooler 3T devices (refer to Attachment 1 for affected catalog and serial numbers)
Date:	03. June 2015
Reference No:	9811109-06/03/15-002-C
Attention:	Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/ Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices
Reason:	Sorin has become aware that the actual disinfection practices and the water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site. Sorin Group is providing this notification to: (1) remind you of the importance of following the company's disinfection and maintenance procedures; (2) inform you that there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination; and (3) provide you with updated Instructions for Use regarding disinfection and maintenance procedures.

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Dear Valued Customer:

The purpose of this letter is to advise you that Sorin Group Deutschland GmbH ("Sorin") is executing a voluntary field safety correction for the Heater Cooler 1T and the Heater Cooler 3T devices ("heater cooler devices"). This field safety notice describes below, immediate action to be taken by you.

- If your heater cooler device has been strictly maintained according to the Instructions for Use, please strictly adhere to the new Instructions for Use provided in **Attachment 1** of this letter.
- If your heater cooler device has not been strictly maintained according to the Instructions for Use, please perform the steps included in the *Immediate Customer Action* section of this letter.

Description of Issue

Sorin has become aware of cases of non-tuberculous mycobacteria endocarditis or deep infection following cardiac surgery during which the heater cooler device was used. There is a risk that surgical patients may experience invasive cardiovascular infection, including endocarditis, or other deep-surgical-site infections due to non-tuberculous mycobacteria, such as Mycobacterium chimaera. Because the symptoms may be slow to manifest, it is possible that many months may pass after completion of the surgical procedure before a surgical patient presents with an infection. In some cases, it is possible that infection could lead to death. Sorin's investigation into these cases is ongoing. To date, the investigation has not determined a causal connection between the heater cooler device and these cases. In some instances there has been a suggestion of such a link; however, infection following cardiac surgical procedures can be caused by numerous, other sources.

The heater cooler device which is provided non-sterile may develop highly contaminated water due to the failure to follow the instructions for Use for water maintenance and water circuit disinfection. If contaminated water is used in the device and the user performs inadequate maintenance and/or fails to strictly adhere to the user instructions for cleaning of the heater cooler device, the device could become a source for contaminating the surgical environment. This condition can occur where there has been a build-up of biofilm within the water circuit of the device. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site.

Contamination of heater cooler units with other waterborne pathogens, like *Mycobacterium abscessus* and non-fermenting gram-negative bacteria, has also been detected in the water of certain heater cooler units. However, no cases of patient infection have been determined to be caused by heater cooler devices. Further, Sorin's investigations into the potential association of heater cooler units with infections by *Mycobacterium chimaera* and other pathogens are ongoing.

If there is a need for further communication based on the investigation results, we will provide you the information.

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Immediate Customer Action

- ✓ Sorin reminds its customers using heater cooler devices about the importance of adhering to correct maintenance of the device at all times and, in particular, to assure that the cleanliness of the water is maintained. **Attachment 1** of this notification includes the new Instructions for Use for the cleaning and disinfection of the Sorin heater cooler devices. Please discard the existing IFU and follow this new IFU which includes updated cleaning and disinfection instructions.
    - o Assure that your team understands Mycobacteria and the potential contamination risks for cardiac surgical procedures, for example, that Mycobacterium is widely distributed in the ecosystem including chlorinated drinking water from the tap, it is inherently resistant to chemical disinfectants and antibiotics, and under the right conditions, it has a propensity to form biofilm and it can also be aerosolized.
- ✓ Healthcare providers involved in the care of patients who have undergone open heart surgery should be vigilant for cases of endocarditis or other cardiovascular infection of unidentified origin with specific testing for slow-growing non-tuberculous Mycobacteria such as *Mycobacterium chimaera* performed as indicated.
- ✓ Verify that this letter has reached your local team and that the recommended monitoring has been considered for your cardiac surgery operating rooms and area. This includes the monitoring of the area water not only for typical microorganisms, but also for slow growing non-tuberculosis Mycobacteria that requires special monitoring practices.

Actions to be taken by the user on the device

- ✓ Review your inventory and identify any heater cooler devices per the attached list, **Attachment 2.**
- ✓ For each unit, determine if the device has been maintained according to the Instructions for Use. If yes, strictly adhere to the new Instructions for Use provided in **Attachment 1** of this notification.

Note: It is recommended to implement a microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous Mycobacteria on a monthly basis (Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria should not be detectable in 100ml). The water in the device should meet microbiological drinking-water quality according to national drinking-water standards.

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AT THE HEART OF MEDICAL TECHNOLOGY

✓ If the device has not been maintained according to the Instructions for Use, follow instructions in the table below:
Note: Please consult your Infection Control Manager for executing the following steps.

Step 1 / Submission of Test Sample
✓ Take two 100ml or greater water samples from one of the drain valves at the back of the device prior to the disinfection step: (1) for heterotrophic plate count measurement; and (2) for non-tuberculous mycobacteria analysis.
✓ Submit samples (1 & 2) to a microbiological lab for heterotrophic plate count measurement of the water and to determine if non-tuberculous mycobacteria are detectable.
✓ Perform disinfection of the water circuit of the heater cooler device(s) according to the new instructions for use provided in **Attachment 1** of this notification.
✓ Replace any accessories and products that are used in conjunction with the heater cooler device which may be potentially contaminated (e.g. tubing and connectors, graduated beaker, warming blanket) by new or re-processed parts.
✓ While awaiting test results from the microbiological lab, operate the heater cooler device outside of the operating room, if structurally possible, and proceed to **Step 2.** Note: For technical support regarding the installation outside the OR (max. distance, routing) please contact your local service representative.
✓ If it is not possible to move the heater cooler device outside the operating room, take the device out of service or proceed to **Step 3.**
Step 2 / Interim Process (if heater cooler device can be operated outside the operating room)
✓ Perform the water maintenance and disinfection of the water circuit of the device(s) according to the new instructions for use provided in **Attachment 1** of this notification.
✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior disinfection.
✓ When you receive the results from the lab go to **Step 4**

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Step 3 / Heater Cooler operated in operating room
✓ Place the heater cooler in a way that the flow conditions of the surgical side are not disturbed by the heater cooler device fans. o Maintain maximum distance from surgical field; o Position heater cooler such that the fan exhausts of the device are directed away from the surgical field; o Position heater cooler fan exhausts close to the suction exhaust (outtake) of the operating room. ✓ The water in the tank must be changed **every day.** ✓ In order to prevent microbial growth and to avoid biofilm build-up, add medical grade 3% hydrogen peroxide solution to the tank contents (follow instructions provided in the new IFU, which direct 150 ml for the heater cooler 3T or 50 ml for the heater cooler 1T). ✓ Perform a **weekly** disinfection as described in the new IFU to kill the waterborne pathogens such as non-tuberculous mycobacteria. ✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior to disinfection. ✓ Take microbiological air samples for non-tuberculous mycobacteria in the operating room when the heater cooler is running on a bi-weekly basis. ✓ When you receive the results from the lab go to **Step 4**
Step 4 / Review of Lab Analysis and Action
✓ If the microbial counts are within the specified limits (meet microbiological drinking-water quality and Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria are not detected in 100ml), the device can be placed back into the operating room. Continue to use and maintain the device according to the new IFU, **Attachment 1** ✓ Implement a microbiological monitoring of the water quality, including monitoring for non-tuberculous Mycobacteria on a monthly basis. ✓ If you find microbial counts in the water are greater than the limits specified above, contact your infection control manager to determine appropriate actions and immediately contact your service representative for support. ✓ If non-tuberculous mycobacteria are found in the air of the operating room, when the heater cooler is operated, remove the heater cooler from service and immediately contact your service representative for support. o For emergency surgeries please consult your infection control manager to determine appropriate actions.

For technical support please contact your local service representative.

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Please complete and return the attached Confirmation Form (see **Attachment 3**) by fax to «Number» or by email to «E-mail Address».

Transmission of this Field Safety Notice

Please assure within your organization that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please communicate this information to them and also inform the below mentioned contact person.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

For questions regarding this Field Safety Notice, please contact Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agencies who are aware of these actions.

Thank you for your cooperation in this matter. Sorin Group is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

i.V. Christian Peis
Director Quality Assurance

Enclosures:

Attachment 1: New Instructions for Use

Attachment 2: Affected Product List

Attachment 3: Customer Response Form

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Attachment 2
Affected Product List

FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
16-02-50	Heater-cooler 1T, 230V	16S00808 - 16S02268
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385

Please refer to Attachment 3 for affected Systems at your site.

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Attachment 3 -
Customer Response Form

FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

According to our records you have the following affected products:

<Fill in the customer related codes and serial numbers only- Use Attachment 4_Product trace list (Excel File)>

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form to:

Sorin Site/ Distributor Name:	<<Print Your Company name here>>
Country:	<<Print Your Country here>>
Contact Name:	<<Print Your Contact Name here>>
E-mail:	<<Print Your E-mail address here>>
Fax No.:	<<Print Your Fax No. here>>
Phone Number:	<<Print Your Phone No. here>>

Section 1 - Please Complete:

1. We HAVE reviewed and understand the attached Field Safety Notice ☐ yes ☐ no
2. We DO NOT understand the attached Field Safety Notice and request more information ☐ yes ☐ no
3. WE HAVE discarded the old Instruction for use ☐ yes ☐ no

Please contact us:

Christian Pels, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

Customer Name:	<<Print Your Company name here>>
Country:	<<Print Your Country here>>
Contact Name:	<<Print Your Contact Name here>>
E-mail:	<<Print Your E-mail address here>>
Fax No.:	<<Print Your Fax No. here>>
Phone Number:	<<Print Your Phone No. here>>
Submitted by	.....
Signature	.....
Date	...../...../.....

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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Sorin Group Deutschland GmbH 12/29/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

DEC 29, 2015

WARNING LETTER

VIA UNITED PARCEL SERVICE

André-Michel Ballester
Chief Executive Officer
LivaNova (formerly Sorin Group S.p.A.)
Via Benigono Crespi, 17
Milano, 20159
Italy

Dear Mr. Ballester:

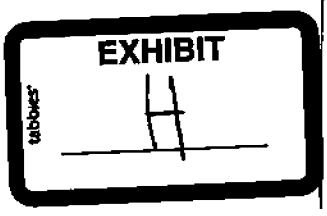
The United States Food and Drug Administration (FDA) conducted the following inspections at your facilities:

- Sorin Group Deutschland GmbH, Lindberghstrasse 25, Munchen, 80939, Germany, (Munchen Facility), dated August 24, 2015, through August 27, 2015; and
- Sorin Group USA, Inc., 14401 W. 65th Way, Arvada, Colorado 80004, U.S.A., (Arvada Facility), dated August 24, 2015, through September 1, 2015.

During the inspection at your Munchen facility, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Stockert Heater Cooler 3T thermal regulator devices. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

These inspections revealed that your firm's devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from Mr. Thierry Dupoux, Vice President, Sorin Group Cardiopulmonary BU, Sorin Group Deutschland GmbH, dated September 15, 2015, concerning our investigator's observations noted on the Form FDA 483s (FDA 483), List of Inspectional Observations, which was issued to your firm's Munchen, Germany facility. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:



1. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i) [Munchen Facility]. For example:

a. Your firm created Design Change Order #8115, dated December 11, 2012, as part of the corrective actions to the FDA Warning Letter dated August 2, 2011, to the Munchen Facility, to address deficiencies in the design change procedures. The change order documents the decisions to change the design input for water quality to add new cleanliness criteria, test the cleaning instructions for use (IFU) to the new input, update the cleaning instructions for use, and validate the new IFU. However:

i. The changed design input is incomplete in that there is no information on how maintaining a cleanliness standard for drinking water applies to the requirement that "biofilm should not grow in the 3T devices". Additionally, there is no information on a water quality standard ensures that the device does not cause waterborne infection; and,

ii. The design validation for the change to the cleaning IFU is inadequate. In the IFU, end users are responsible for conducting the cleaning and disinfection procedure on devices at user facilities. There is no documentation that your firm tested the updated IFU under actual or simulated use conditions to ensure the usability of the cleaning IFU. Your firm has received complaints of patient deaths due to infection from non-tuberculosis mycobacteria (NTM), specifically *mycobacteria chimaera*, since January 2014, where the cause of the infection appeared to be 3T devices colonized with the mycobacteria. Your firm investigated the complaints and determined that the user facilities had not been following the cleaning IFUs, potentially contributing to patient infections.

b. Your firm issued Design Change Orders 9416, 9416-01, 9711, and 9690, corresponding to CAPA 2015-03, and submitted a recall in June, 2015 (#Z-2076/2081-2015), to update the cleaning and disinfection IFU after receiving complaints of patient deaths due to infections caused by the 3T device. As part of this design change, your firm contracted a laboratory to conduct a test on the cleaning procedure in the updated IFU. The resulting test report, dated April 7, 2015, describes the test protocol and results. However, your firm's test report does not demonstrate an adequate verification or validation of the new cleaning IFU because: (reduction) for bacteria, as required by your test procedure. In addition the acceptance criteria do not appear to correspond to the design inputs of drinking water quality, controlling biofilm, or that the device does not cause waterborne infection;

i. The acceptance criteria for the test do not demonstrate that the updated cleaning and disinfection instructions produce a (b)(4) level (reduction) for bacteria, as required by your test procedure. In addition the acceptance criteria do not appear to correspond to the design inputs of drinking water quality, controlling biofilm, or that the device does not cause waterborne infection;

ii. Puristeril is not available in the United States, and therefore your firm recommends using Clorox as a substitute in the IFUs. However, the test report does not demonstrate the amounts of Clorox described in the IFU are equivalent to Puristeril;

iii. Two of the challenge bacteria, (b)(4) and (b)(4), used in the test procedure were not used at a high enough concentration to demonstrate the (b)(4) level acceptance criteria;

iv. The exact disinfectant dilution is not clear, because the exact water amounts used were not measured. Water levels were determined by (b)(4). No validation for the accuracy of these (b)(4) for detecting water levels was documented in the test report;

v. There is no description for how the sampling locations, sampling methods, and machine conditions used represent worst case condition for finding bacteria;

vi. There is no statistical rationale documented in the test report for using testing (b)(4), to demonstrate that the cleaning instructions for use will consistently maintain water quality requirements inside 3T devices in the field or clinical setting; and,

vii. There is no documentation that your firm tested the updated IFUs for usability by the end user. Specifically, those responsible for conducting the cleaning and disinfection procedure on devices at user facility.

Your firm's response did not address this deficiency. We note that this is a repeat from a nonconformance noted in the Warning Letter issued to the Munchen facility on August 2, 2011.

2. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a) [Munchen facility]. For example, your firm designed and implemented a new cleaning, drying, and disinfection process using (b)(4) at the contract manufacturer, (b)(4), as part of a corrective action. However, the new process was not adequately validated or verified prior to implementation on production units or monitored after implementation. Specifically:

a. Your firm contracted an "efficacy test" at a testing firm, (b)(4), on November 17, 2014, to conduct an in-house validation of the use of the (b)(4) disinfection and drying process to eliminate a mycobacterium test strain from 3T devices to validate the new process. However, the efficacy test was not an adequate verification or validation of the disinfection and drying process because:

i. The efficacy test report documented testing to (b)(4) mixture; however, the disinfection and drying process (b)(4). There was no documentation of justification for using a different concentration, and therefore the test does not accurately reflect the (b)(4) disinfection procedure;

ii. No controls were used in the efficacy test;

iii. Your firm did not provide documentation to describe if a (b)(4) was used (b)(4); and

iv. Your firm did not provide documentation for how the bacteria were (b)(4).

b. Your firm conducted further monitoring of manufactured devices after the (b)(4) disinfection and drying process was implemented. However, the monitoring was inadequate because the following required information for a cleaning and disinfection monitoring report was not documented:

i. The data for recovery efficiency of bacteria from the 3T devices;

ii. The data for complete bioburden: aerobic bacteria, anaerobic bacteria, spores, fungi, and yeast in the devices prior to disinfection. Only aerobic mesophilic bacteria are noted;

iii. The data for bacteriostasis or fungistasis;

iv. The concentration of (b)(4) used in sampling;

v. The time of exposure to the (b)(4); and

vi. Whether (b)(4) was performed after (b)(4).

c. Your firm's disinfection and drying procedure and validation protocol, "(b)(4) cleaning, disinfection, and drying process designed and implemented by your Munchen facility at the contract manufacturer (b)(4). However, the procedure was not adequately validated to ensure that the process completely dries the device.

For example:

i. The protocol states that the transparent pump tubing (b)(4) The protocol did not indicate whether any (b)(4) after drying was acceptable; and

ii. The validation did not include key technical parameters required for validation of a disinfection process. For example:

a. The amount of **(b)(4)** at time 0 (start of experiment);

b. Data to provide a rationale for choosing **(b)(4)** dry the tanks and tubing;

c. Quantification of the term "visually dry" and how to measure dryness by a validated method;

d. Documentation of the **(b)(4)**; and

e. Documentation of environmental conditions for temperature and humidity during the **(b)(4)** device prior to sampling.

We reviewed your firm's response and conclude that it is not adequate. Your firm did not evaluate the potential impact of these violations on distributed devices, and take steps to mitigate the risks as needed.

Our inspection also revealed that your firm's devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR), but are not limited to, the following:

3. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17 (Arvada facility). For example:

Your firm's MDR procedure, "Standard Operating Procedure for Medical Device Reporting", **(b)(4)**, Rev. AA, updated on October 15, 2012, has the following deficiencies:

a. The procedure does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example, the procedure omits definition of the term "reasonably suggests," found in 803.20(c)(1). The exclusion of this definition for this term from the procedure may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a);

b. The procedure does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the procedure does not address how your firm will submit all information reasonably known to it for each event;

c. The procedure does not describe how it will address documentation and record-keeping requirements, including:

i. Documentation of adverse event related information maintained as MDR event files'

ii. Information that was evaluated to determine if an event was reportable;

iii. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable; and

iv. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

In addition, we have noticed deficiencies in your firm's (Munchen facility) MDR procedure, "**(b)(4)**, Rev. 003. Specifically, the MDR procedure does not have an effective date.

Please note, the MDR procedures at the Munchen and Arvada facilities include references to submitting MDRs to FDA using the following address: FDA, CDRH, Medical Device Reporting, P. O. Box 3002, Rockville, MD 20847-3002. Please note that effective August 14, 2015, MDRs should be submitted electronically and paper submissions will not be accepted, except under special circumstances, directed by FDA. For more information about electronic reporting, please refer to the eMDR website and the eMDR guidance document.
http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm
(http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm)

Our inspection at your Munchen facility also revealed that the Heater Cooler 3T device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The Heater-Cooler System 3T is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

Specifically, your firm distributed the Heater-Cooler System 3T, cleared under K052601, with modified Instructions for Use (Versions 013 and 014) with respect to the operating, maintaining, cleaning and disinfecting of the device. Some of the modifications found in Versions 013 and 014 include: adding more instruction details, changes to the cleaning/disinfecting process (e.g., chemicals used and amounts used), and expansion to the process to include the entire circuit instead of only the tanks. These are significant labeling changes that can affect the safety or effectiveness of the device, and therefore require a new 510(k) in order to be assured that appropriate testing and validation of the cleaning/disinfecting protocols have taken place.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency, 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for the device is described on the Internet at:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm.
(/MedicalDevices/default.htm)

The FDA will evaluate the information that you submit and decide whether your product may be legally marketed.

Our inspections also revealed that your firm's Heater-Cooler System 3T devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806 – Medical Devices; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

Failure to submit a written report to FDA of any correction or removal of a device initiated to remedy a violation of the act caused by the device which may present a risk to health, as required by 21 CFR 806.10. For example: A change order was initiated on December 20, 2011, related to a change consisting of updating the devices' IFU to indicate a new cleaning and disinfection procedure. Subsequently, the change was implemented in the IFU to indicate the use of a water filter and to add Hydrogen Peroxide to the water used in the devices. A letter was sent to your customers notifying them of the new IFU. The letter stated that the instructions for the device had been updated to assure the user can maintain the cleanliness of the water in the device, and that the 'Updated Instructions for Water Cleanliness' replaced the previous water cleaning instructions for the 3T Heater Cooler. Your firm did not submit a written report to FDA of the correction and removal, as required by 21 CFR 806.

Given the serious nature of the violations of the Act, the Heater Cooler 3T devices, and other devices manufactured by your Munchen facility are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these

devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office, in writing within fifteen business days from the date you receive this letter, of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993.Refer to CMS case #484629 when replying. If you have any questions about the contents of this letter, please contact: Shumaya Ali, Acting Chief, Foreign Enforcement Branch, at feb@fda.hhs.gov (email), or +1 (240) 402-4020 (phone), or +1 (301) 847-8139 (fax).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
CAPT Sean Boyd
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Cc:
Thierry Dupoux
Vice President of Quality Assurance and Regulatory Affairs
LivaNova (formerly Sorin Group Deutschland GmbH)
Lindberghstrasse 25
Munchen, 80939
Germany

Carrie Wood
Director
Customer Quality
LivaNova (formerly Sorin Group USA)

14401 W 65th Way
Arvada, CO 80004

More in 2015
(/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
EDWIN SPINKS

DEFENDANTS
Liva Nova PLC, Sorin Group Deutschland GMBH, and Sorin Group USA, Inc.

(b) County of Residence of First Listed Plaintiff SANGAMON
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant unknown
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
GEISLER LAW OFFICES, 241 S. MAIN STREET, DECATUR, ILLINOIS 62523; PHONE NUMBER (217) 423-8081

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. § 1332

Brief description of cause:
Defective Pharmaceutical Device

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):
JUDGE DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD
Gary F. Geisler

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE