UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA

DEBRA PRESCOTT, in Her Own Right and as Executor of the Estate of RONALD STANLEY PRESCOTT,	**CIVIL ACTION**
Plaintiff,	**NO:**
v.	
LIVANOVA PLC, SORIN GROUP DEUTSCHLAND GMBH, and SORIN GROUP USA, INC.	**JURY TRIAL DEMANDED**
Defendants.	

CIVIL COMPLAINT

Plaintiff, Debra Prescott, in her own right and as Executor of the Estate of Ronald Stanley Prescott, by way of Complaint against Defendants, LivaNova PLC, Sorin Group Deutschland GMBH and Sorin Group USA, Inc., alleges as follows:

JURISIDCTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 USCS § 1332(a)(2). Plaintiff is a citizen and resident of the State of Iowa. Defendant, LivaNova PLC, is a foreign corporation incorporated under the laws of England and Wales with a corporate headquarters in London. Defendant, Sorin Group Deutschland Gmbh, is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA Inc. has a principal place of business in Arvada, Colorado.

2. Personal jurisdiction exists over Defendants, LivaNova PLC and Sorin Group Deutschland Gmbh, in the U.S. due to the general and specific contacts they maintain in the U.S.

Defendants maintain those contacts presently and did so at all times material to this action. The amount in controversy exceeds $75,000.

3. Venue is proper in this District pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction and Defendants conduct substantial business within this jurisdiction.

THE PARTIES

4. Plaintiff, Debra Prescott, is the widow of Ronald Stanley Prescott and an adult individual and citizen of the state of Iowa residing at 1017 Kennedy St., Ames, Iowa 50010. On July 11, 2016, Plaintiff, Debra Prescott, was named the Executor of Ronald Prescott's estate by order of the Iowa District Court for Story County

5. Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation incorporated under the laws of England and Wales with a headquarters in London. LivaNova is a global medical device company specializing in, among other products, devices used in the treatment of cardiovascular diseases. LivaNova pursuant to a merger agreement between Sorin Group S.p.A[1] and non-party, Cybertronics, Inc., advised purchasers in the United States it is the responsible party for the Sorin 3T Heater-Cooler System at issue herein. Further, LivaNova has exclusively communicated with the Food and Drug Administration ("FDA") and other interested parties with respect to safety concerns about the 3T System. *See* the letters attached as Exhibits A through C.

[1] Upon information and belief, Sorin Group S.p.A. was the original holding company of Defendants, Sorin Group Deutschland Gmbh and Sorin Group USA, Inc.

6. Defendant, Sorin Group Deutschland Gmbh ("Sorin") is a foreign for profit corporation headquartered in Munich, Germany. Sorin initially designed, manufactured and marketed the Sorin 3T Heater-Cooler System. In October 2015, Sorin merged with and into LivaNova, with LivaNova continuing as the surviving company.

7. Defendant, Sorin Group USA, Inc. ("Sorin USA") is a U.S. designer, manufacturer, marketer and distributor of the Sorin 3T Heater-Cooler System, with a principal place of business in Arvada, Colorado. As set forth in LivaNova's Form 10-Q filed with the Security and Exchange Commission, Defendants, Sorin and Sorin USA, are wholly owned subsidiaries of LivaNova. Each Defendant markets and sells products under the LivaNova name.

GENERAL FACTUAL ALLEGATIONS

8. On or about February 2, 2016, the University of Iowa Hospitals and Clinics ("UIHC") announced that 1500 of its patients who had major heart, lung and liver surgeries between January 1, 2012 and January 22, 2016 had been exposed to a rare and potentially fatal bacteria via Sorin 3T Heater-Cooler Systems used to regulate blood temperature.

9. The bacterium at issue, *M. Chimaera*, is a subspecies of nontuberculous mycobacterium ("NTM") that occurs naturally in the environment and rarely causes illness. However, NTM poses a unique risk to patients whose organs and chest cavities are directly exposed to the bacteria during surgery.

10. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to four years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease.

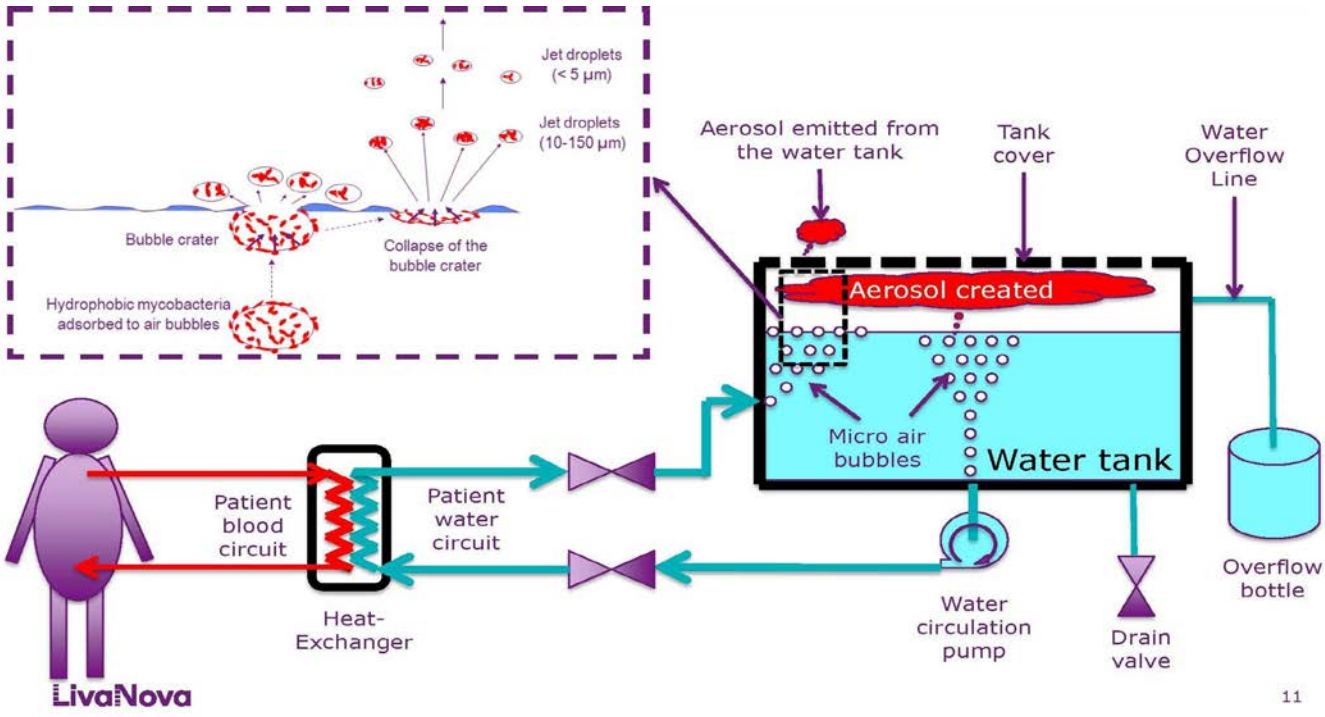
11. Symptoms of NTM infection are non-specific and may include any of the following: fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss and fatigue.

12. The diagnosis of an NTM infection requires targeted culturing and/or molecular diagnostic testing.

13. While an NTM infection diagnosed early on may be successfully treated with a series of antibiotics, there is a significant risk of death in cases diagnosed late and in individuals with considerably weakened immune systems.

A. Defendants' 3T Heater-Cooler Systems as the Infection Source

14. The 3T System regulates blood temperature by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. The water tanks and other areas where water pass through aerosolize a vapor containing NTM which exits out of the device and is pushed into the ambient air of the operating room through the System's exhaust fan. If placed in the operating room, the contaminated vapor from the System directly enters the sterile surgical field and the patient's open body.



(taken from LivaNova's presentation to the FDA Circulatory Devices Panel on June 2, 2016, publicly available)

15. The potential for contaminated water from heater-cooler devices to infect patients intraoperatively was recognized by the medical and scientific community as early as November 2002.[2]

16. Invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.[3]

[2] *See* The Heater-Cooler Unit—A Conceivable Source of Infection, Weitkemper, *et al*., The Journal of the American Society of Extra-Corporeal Technology, 2002.
[3] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf (last accessed on July 29, 2016).

17. A public health investigation in Switzerland following six patient infections since 2011 included microbiological examinations of environmental samples that identified *M. Chimaera* contamination in heater-cooler units, including water samples from inside the units. Samples of the ambient air were positive for *M. chimaera* when the units were running, but negative when they were turned off. [4]

18. On October 21, 2015, the U.S. Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication to raise awareness among health departments, healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

19. The 3T Systems used at UIHC from January 1, 2012 to January 22, 2016 were designed, manufactured, marketed and/or sold by Defendants LivaNova, Sorin and Sorin USA.

20. On July 15, 2015, Defendants issued a Class 2 Recall of the 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

21. The recall directed customers to follow the new cleaning and disinfection procedures outlined in a Field Safety Notice issued by LivaNova and/or Sorin on June 15, 2015.

22. According to this Field Safety Notice, the company's hygiene concept was "enhanced" by introducing the following modifications:

a) Use filtered tap water when filling the device;

[4] *Id.*

b) To make disinfection easier, switch from three different cleaning procedures (every five days, every two weeks and every three months), to just two (every seven days and every fourteen days);

c) The option to use peracetic acid instead of Clorox for disinfection;

d) Use hydrogen peroxide in low dose for device preservation;

e) Include all external tubing, bottles and buckets in the disinfection process;

f) Change to polyethylene tubing that meets national drinking water standards; and

g) Unused heater-coolers should be disinfected bi-weekly.

23. A month prior to the recall, in May 2015, LivaNova and/or Sorin informed customers that devices that had not been maintained according to the manufacturers' instructions for use ("IFUs") for a long period of time required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

24. Upon information and belief, LivaNova and/or Sorin knew or should have known that design and/or manufacturing defects in its 3T System renders it prone to bacterial colonization and transmission, *regardless of the cleaning and disinfection procedures used*.

25. Manufacturing and User Facility Device Experience ("MAUDE") reports, such as one reported to the FDA on July 7, 2016, evidence that even mechanical deep disinfection followed by the use of filtered water, new water hoses, and three cycles of Defendants' new cleaning procedure fail to eliminate high bacteria counts in the 3T System.[5]

[5] *See also*, ECDC Rapid Risk Assessment, *supra* ("In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for *M. Chimaera* at the hospital tested positive three months after purchase and installation.")

B. Additional NTM Outbreaks and Regulatory Agency Responses

26. The risk of NTM transmission with the 3T System is not unique to UIHC. In October and November 2015, two Pennsylvania hospitals notified approximately 3600 patients who underwent open heart surgeries between October 1, 2011 and November 5, 2015 of their exposure to NTM through use of the 3T System.

27. To date, there have been eleven (11) confirmed NTM infections in Pennsylvania which have resulted in five (5) deaths.

28. Hospitals in at least 15 U.S. states have reported patient infections and/or device contamination with NTM. For example, in May 2016, Swedish Medical Center in Seattle, Washington issued letters notifying cardiac bypass patients who had surgery since May 2012 that it had tested and found NTM in several of its 3T Systems.

29. Many hospitals have now either discontinued using the 3T System or, like UIHC, have moved the System into a separate room to prevent contaminated aerosols from reaching the surgical field.

30. On December 29, 2015, the FDA sent LivaNova a warning letter advising the company that its 3T Systems were subject to refusal of admission into the U.S. until it resolved several FDA violations, including the FDA's determination that the 3T Systems were adulterated[6] and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions. The FDA's findings

[6] Under the Federal Food, Drug and Cosmetic Act, a medical device is "adulterated" if the methods used in, or the facilities or controls used for their manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation.

were based on its inspections of the company's Munchen, Germany and Arvada, Colorado production facilities.

31. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been documented, validated and/or submitted to the FDA for approval.

32. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, which had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

33. In April 2016, a Euro Surveillance study following environmental investigations conducted between July 2014 and June 2015 determined that certain 3T Systems manufactured at LivaNova's Munchen, Germany production facility were contaminated with NTM on the production line or elsewhere at Defendants' manufacturing facility.

34. A June 1, 2016 FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the M. Chimaera to which European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model—the 3T." The FDA cautioned U.S. purchasers of the 3T that if they purchased their units before September 2014 they may have been shipped from Defendants' factory contaminated with *M. Chimaera*.[7]

35. In June 2016, a study published in the Journal of Emerging Infectious Diseases confirmed the airborne transmission of NTM via 3T Systems due to the ability of the System's

[7] June 1, 2016 FDA Safety Communication, available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm (last accessed on August 9, 2016).

exhaust fan to disrupt the ultraclean air ventilation systems of operating rooms. According to the study, aerosolization from the 3T carried *M. Chimaera* particles a distance of up to 5 meters from the device.

36. On June 2-3, 2016, the FDA hosted a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the 3T System.

37. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports ("MDR") it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the 3T System.

MDRs by Manufacturer, Brand Name and User Facility (US vs. OUS)

MDRs by Manufacturer and UF				
Manufacturer and Brand Name	Total Number of MDRs	Number of User Facilities Represented in the MDRs		
		US	OUS	Total
LivaNova/Sorin** Stockert 3T	160	15	35	50
Maquet HCU20, HCU30 & HCU40	9	0	5*	5*
Cincinnati Sub-Zero 333W and Hemotherm	3	2*	0	2*
Terumo HX2	8	1*	0	1*
Total	180	16 (2*)	39 (1*)	55 (3*)

*Note that 3 UF reported devices from 2 different manufacturers
**LivaNova/Sorin has approximately 60% of the market share for this type of device

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38. During this Panel, a LivaNova representative admitted that the company was in the process of retrofitting existing 3T Systems with new design features, including, but not limited to, changing tubing materials from PVC to polyethylene to limit biofilm formation and the introduction of plugs in the water circuit to prevent sitting water.

C. Factual Allegations Specific to Plaintiff's Decedent, Ronald Stanley Prescott

39. Ronald Prescott underwent a heart valve replacement at UIHC on October 2, 2012.

40. In February 2014, Ronald Prescott presented to Mary Greely Medical Center in Ames, Iowa with complaints of muscle pain, fatigue, night sweats, persistent fever and a dry cough.

41. Medical records from Mary Greely Medical Center evidenced an enlarged spleen, elevated liver enzymes and bilateral pulmonary infiltrates suspicious for sarcoidosis, a multi-organ inflammatory disease.

42. In September 2014, after comprehensive medical testing over the course of several months, Ronald Prescott was positively diagnosed with a disseminated *M. Chimaera* (NTM) infection at Mary Greely Medical Center by way of bone marrow and bronchoscopy cultures.

43. Ronald Prescott subsequently began treatment with a series of powerful antibiotics, many of which caused him to suffer drug-related toxicity, including peripheral neuropathy and significant hearing loss.

44. Despite changes to his treatment plan, monthly blood cultures through December 2015 confirmed the presence of *M. Chimaera.*

45. On or about January 29, 2016, Ronald and Debra Prescott received a phone call from the Director of UIHC's Division of Infectious Diseases informing them of the causative link between the 3T System and NTM infections.

46. Ronald Prescott's treating physicians associated his NTM infection to the heart valve replacement at UIHC in October 2012.[8]

47. Doctors recommended a re-operation to remove the infected device, but Ronald Prescott's unstable medical condition prevented surgery.

48. Moreover, Ronald Prescott could not be guaranteed that removal of the contaminated valve would eliminate the bacteria from his body.

49. Following his NTM diagnosis, Ronald Prescott suffered from 75 pound weight loss, chronic pain and fatigue, nausea, vomiting, chills, persistent low grade fever, chronic kidney disease and a diagnosis of pancreatitis and steroid-induced diabetes.

50. Despite heroic medical treatment for nearly two years with several infectious disease specialists throughout the country, Ronald Prescott's blood, sputum and bone marrow continued to test positive for NTM.

51. Towards the end of his battle with NTM, he unable to ambulate without assistance and relied on a walker and wheelchair.

52. On or about April 12, 2016, Ronald Prescott was admitted to Israel Hospice House in Ames, Iowa where he discontinued all antibiotics and substantial medical intervention.

[8] For example, a treating physician at National Jewish Health in Denver, Colorado stated "this is most likely an endovascular/valvular infection related to postoperative infection from the Sorin heater/cooler units used with bypass surgery".

53. Ronald Prescott passed away on May 14, 2016 at the age of 59. The immediate cause of death was identified as Disseminated Mycobacterium Avium Intracellular Complex infection (NTM).

54. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Ronald Prescott acquired an NTM infection, forcing him to undergo several years of painful medical procedures and treatment, and ultimately, an untimely death.

55. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff, Debra Prescott, expended various sums of money for the medical care and treatment of her husband, Ronald Prescott.

56. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff's decedent, Ronald Prescott, suffered a substantial loss of earning capacity.

57. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff's decedent, Ronald Prescott, suffered excruciating and agonizing physical and emotional pain and suffering.

58. As a further direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff, Debra Prescott, was deprived of the care, comfort, companionship, services and consortium of her husband, Ronald Prescott.

59. As a further direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Ronald and Debra Prescott's two adult children, Paul Michael Prescott and Catharina Leigh Prescott, were deprived of the companionship, comfort, guidance, affection and aid of their father, Ronald Prescott.

60. Plaintiff's decedent, Ronald Prescott, was in no way responsible for his injuries.

COUNT I
Negligence- Design Defect

61. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

62. The 3T System is a product within the meaning of Iowa products liability law.

63. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff's decedent, Ronald Prescott, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

64. Under Iowa products liability law, Defendants, LivaNova, Sorin and Sorin U.S.A, owed Plaintiff and her decedent, Ronald Prescott, a duty to exercise reasonable care in designing and testing the 3T System.

65. Defendants, LivaNova, Sorin and Sorin U.S.A. designed the 3T System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

66. At all times material, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

67. A patient or consumer using the 3T System would reasonably expect the device to be free of significant defects.

68. The 3T System, as designed by the Defendants, colonizes bacteria, including *M. Chimaera*.

69. The 3T System, as designed by the Defendants, directly transmits bacteria, including *M. Chimaera*, to patients during invasive surgery.

70. The foreseeable risks of using the 3T System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T System.

71. Reasonable alternative designs existed for the 3T System which would have eliminated or reduced the risk of bacterial colonization and/or transmission of such bacteria to patients undergoing invasive surgical procedures.

72. Reasonable and feasible alternative designs include, but are not limited to, measures to direct airflow away from the surgical field (i.e. a housing unit for the exhaust vent), reducing the force at which air is vented from the System to a rate of less than 1000 cubic feet per minute, water reservoir isolation by using closed loop fluid management, an open water design to prevent inaccessible airspace, removable lids and parts for easy disinfection, disposable tank liners to prevent biofilm formation, and internal pasteurization or UV features to kill bacteria.

73. The failure to use feasible, reasonable alternative designs that eliminate bacterial colonization and the aerosolization of bacteria into the ambient air of operating rooms renders the 3T System unreasonably unsafe.

74. Defendants knew or should have known as early as 2002 that NTM, or other harmful bacteria, could colonize within the 3T System and be spread to patients during surgery through the exhaust vent.

75. The death of Plaintiff's decedent, Ronald Prescott, was caused by Defendants' conduct as follows:

a) Failing to conduct adequate safety and efficacy testing before placing the 3T System into the stream of commerce;

b) Failing to timely establish procedures for reviewing the design of the 3T System after receiving information that patients were developing bacterial infections as a result of surgeries using the System;

c) Failing to timely establish procedures for validation or, where appropriate, review and approval of design change orders for the 3T System before their implementation as required under 21 CFR 820.30(i); and

d) Failing to design or redesign the 3T System to eliminate or mitigate bacterial colonization and/or transmission of such bacteria.

76. Plaintiff's decedent, Ronald Prescott, was proximately harmed by the aforesaid design defects in the 3T System as described above.

WHEREFORE, Plaintiff, Debra Prescott, in her own right and as Executor of the Estate of Ronald Prescott, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT II
Strict Liability-Manufacturing Defect

77. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

78. The 3T System is a product within the meaning of Iowa products liability law.

79. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff's decedent, Ronald Prescott, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

80. Defendants, LivaNova, Sorin and Sorin U.S.A. manufactured the 3T System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

81. At all times material, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

82. A reasonable patient or consumer of the 3T System would expect that the device be free of significant defects.

83. The 3T System, as manufactured by the Defendants, colonizes bacteria, including *M. Chimaera*.

84. The 3T System, as manufactured by the Defendants, directly transmits bacteria, including *M. Chimaera,* to patients during invasive surgery.

85. The foreseeable risks of using the 3T System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T System.

86. The death of Plaintiff's decedent, Ronald Prescott, was caused by Defendants' conduct as follows:

a) Failing to timely establish procedures or practices to prevent the 3T System from being contaminated with NTM on the production line or elsewhere at Defendants' production facilities;

b) Manufacturing and selling the 3T System with NTM contamination that occurred on the production line or elsewhere at Defendants' production facilities; and

c) Failing to ensure proper workmanship, materials and labeling for the 3T System.

87. Plaintiff's decedent, Ronald Prescott, was proximately harmed by the aforesaid manufacturing defects in the 3T System as described above.

WHEREFORE, Plaintiff, Debra Prescott, in her own right and as Executor of the Estate of Ronald Prescott, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT III
Negligence- Warnings Defects

88. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

89. The 3T System is a product within the meaning of Iowa products liability law.

90. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff's decedent, Ronald Prescott, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

91. Defendants, LivaNova, Sorin and Sorin U.S.A, owed Plaintiff and her decedent, Ronald Prescott, a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling the 3T System.

92. Defendants, LivaNova, Sorin and Sorin U.S.A. marketed, advertised and promoted the 3T System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

93. At all times material, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

94. A reasonable patient or consumer of the 3T System would expect that the device be free of significant defects.

95. The 3T System colonizes bacteria, including *M. Chimaera*, and directly transmits such bacteria to patients during invasive surgery.

96. Defendants knew or should have known as early as 2002 that NTM, or other harmful bacteria, could colonize within the 3T System and be spread to patients during surgery through the exhaust vent.

97. The foreseeable risks of using the 3T System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T System.

98. The death of Plaintiff's decedent, Ronald Prescott, was caused by Defendants' conduct as follows:

a) Failing to provide proper cleaning and disinfection procedures for the 3T System;

b) Failing to conduct proper validation studies to demonstrate the safety and efficacy of cleaning and disinfection procedures for the 3T System;

c) Failing to warn patients like Ronald Prescott and/or purchasers of the 3T System that the System colonized bacteria and unnecessarily transmitted it into the ambient air of operating rooms;

d) Failing to timely notify known purchasers of the 3T System that patients could be exposed to NTM;

e) Failing to alert hospitals and patients to promptly test for NTM infection when patients present with fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss and fatigue after surgery using the 3T System; and

f) Failing to timely notify known purchasers of the 3T System to relocate the device from the operating room during surgery to prevent patient transmission of NTM.

99. Plaintiff's decedent, Ronald Prescott, was proximately harmed by the aforesaid warnings defects in the 3T System as described above.

WHEREFORE, Plaintiff, Debra Prescott, in her own right and as Executor of the Estate of Ronald Prescott, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT IV
Loss of Spousal Consortium

100. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

101. Plaintiff, Debra Prescott, was entitled to the care, comfort, companionship, services and consortium of her husband, Ronald Prescott.

102. As a result of the injuries and wrongful death of Ronald Prescott, Plaintiff, Debra Prescott was and will continue to be deprived of the care, companionship, services and consortium of her husband.

WHEREFORE, Plaintiff, Debra Prescott, in her own right and as Executor of the Estate of Ronald Prescott, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT V
Loss of Parental Consortium

103. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

104. Paul Michael Prescott, age 38, and Catharina Leigh Prescott, age 36, are the adult children of Ronald and Debra Prescott.

105. Paul and Catherina were entitled to the companionship, comfort, guidance, affection and aid of their father, Ronald Prescott.

106. As a result of Defendants' negligence, Paul and Catharina have suffered a loss of parental consortium.

107. On behalf of her children, Plaintiff, Debra Prescott, seeks damages for loss of parental consortium.

WHEREFORE, Plaintiff, Debra Prescott, in her own right and as Executor of the Estate of Ronald Prescott, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

PRAYER FOR RELIEF

Plaintiff, Debra Prescott, in her own right and as Executor of the Estate of Ronald Prescott, requests the Court to enter judgment against the Defendants as follows:

A. An award to Plaintiff of compensatory and punitive damages, costs and reasonable attorneys' fees, as permitted by law;

B. An award of pre-judgment and post-judgment interest, as provided by law;

C. Leave to amend this Complaint to conform to the evidence produced at trial; and

D. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues so triable.

Dated: August 19, 2016

Respectfully submitted,

ANAPOL WEISS

/s/ Sol H. Weiss

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Counsel for Plaintiff, Debra Prescott

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

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.

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
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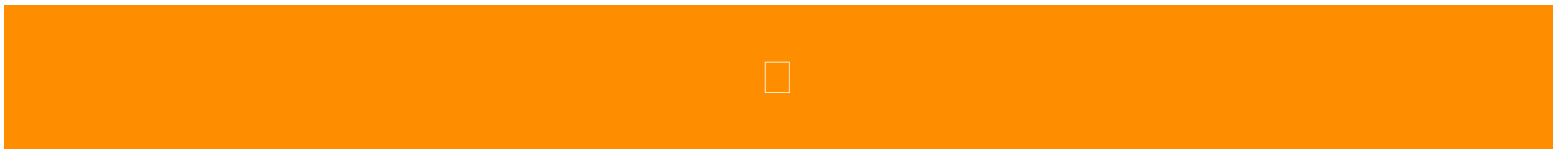

Jan 05, 2016

LivaNova PLC Provides Update on FDA Warning Letter

LONDON, Jan. 05, 2016 (GLOBE NEWSWIRE) -- LivaNova PLC (NASDAQ:LIVN) (LSE:LIVN) (the “Company”) received a Warning Letter dated December 29, 2015, from the United States Food and Drug Administration (“FDA”) alleging certain violations of FDA regulations applicable to medical device manufacturers at its Munich, Germany and Arvada, Colorado facilities.

The Company currently believes that less

results. Further meetings are planned with FDA in order to clarify certain aspects of the Warning Letter.

FDA inspected the Company's Munich facility from August 24, 2015, to August 27, 2015, and its Arvada facility from August 24, 2015, to September 1, 2015. On August 27, 2015, FDA issued a Form 483 identifying two observed non-conformities with certain regulatory requirements at the Munich facility. The Company did not receive a Form 483 in connection with FDA's inspection of the Arvada facility.

Following the receipt of the Form 483, the Company provided written responses to FDA describing corrective and preventive actions that were underway or to be taken to address FDA's observations at the Munich facility. The Warning Letter responded in part to the Company's responses and identified other alleged violations not previously included in the Form 483. The Company will continue to work diligently to remediate FDA's inspectional observations for the Munich facility as well as the additional issues identified in the Warning Letter. The Company takes these matters seriously and intends to respond timely and fully to FDA's requests.

The Warning Letter states that the 3T Heater Cooler devices, and other devices

manufactured by the Company's Munich facility, are subject to refusal of admission into the United States until resolution of the issues set forth in the Warning Letter. FDA has informed the Company that the import alert is, at the present time, limited to the 3T Heater Cooler devices but that the agency reserves the right to expand the scope of the import alert if future circumstances warrant such action. The Warning Letter did not request that existing users cease using the 3T Heater Cooler device, and to help clarify the Warning Letter, the Company has issued an informational Customer Letter. The Company is working constructively with FDA to reduce the impact of this decision on existing U. S. customers of 3T Heater Cooler devices, and the Company will promptly communicate to its customers and users of the 3T Heater Cooler any updates agreed upon with FDA in this regard. Manufacturing and shipment of all of the Company's products other than the 3T Heater Cooler are unaffected by this limitation at the present time and will continue as normal.

Lastly, while the Warning Letter states that 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, the Company notes that this Warning Letter only specifically names the

Munich and Arvada facilities, which do not manufacture or design devices subject to premarket approval.

About LivaNova

LivaNova PLC, headquartered in London, UK, is a global medical technology company formed by the merger of Sorin S.p.A, a leader in the treatment of cardiovascular diseases, and Cyberonics Inc., a medical device company with core expertise in neuromodulation. LivaNova transforms medical innovation into meaningful solutions for the benefit of patients, healthcare professionals, and healthcare systems. The company employs approximately 4,500 employees worldwide. With a presence in more than 100 countries, LivaNova operates as three business units: Cardiac Rhythm Management, Cardiac Surgery, and Neuromodulation, with operating headquarters in Clamart (France), Mirandola (Italy) and Houston (U.S.A.), respectively.

LivaNova is listed on NASDAQ and listed on the Official List of the UK's Financial Conduct Authority and traded on London Stock Exchange (LSE) under the ticker symbol "LIVN".

For more information, please visit www.livanova.com, or contact:

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LivaNova Plc

LivaNova
Health innovation that matters

SORIN GROUP
Cyberonics

January 2016

Dear Valued Customer,

The purpose of this letter is to inform you about changes in the availability of the 3T Heater-Cooler System ("3T") in the United States resulting from a Warning Letter issued by the U.S. Food and Drug Administration ("FDA" or "the agency") dated December 29, 2015. The Warning Letter alleged certain violations of FDA regulations applicable to medical device manufacturers at its Munich, Germany and Arvada, Colorado facilities, to which LivaNova intends to respond in a timely manner.

The Warning Letter did not request that existing users cease using the 3T Heater Cooler device. Customers may continue to use the 3T device in accordance with our current Operating Instructions. To this end, we refer you to the Field Safety Notice regarding the Heater-Cooler 3T Devices (Reference #9611109-06/03/15-002-C, dated June 15, 2015 and updated August 6, 2015). Please continue to perform regular maintenance and disinfection of your 3T devices according to the latest Operating Instructions, which can be found at http://www.livanova.sorin.com/3T.

As a result of these issues, FDA has decided to limit the importation of the 3T device into the United States. The Company is working constructively with FDA to reduce the impact of this decision on you, and the Company will promptly communicate to you any updates agreed upon with FDA in this regard. Manufacturing and shipment of all of the Company's products other than the 3T Heater-Cooler are unaffected by this limitation at the present time and will continue as normal.

We are working diligently and in communication with FDA to resolve these issues as quickly as possible. We are committed to providing the highest quality products and service to our customers. We are also collaborating with U.S. medical societies to ensure that we properly and effectively communicate updates related to the adequate disinfection of our 3T Heater-Cooler devices. We will continue this practice of rapid and full disclosure in the future.

SORIN GROUP Deutschland GmbH
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of LivaNova PLC

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LivaNova
Health innovation that matters

SORIN GROUP
Cyberonics

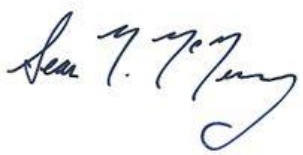
Contact Information:

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

Email: 3T.US@LivaNova.com
Technical Services Hotline: 1-800-221-7943, Ext: 6355
3T Voicemail Box: 1-303-467-6601

Thank you for your continued support and cooperation in this matter. We apologize for any inconvenience this situation may have caused for you and your teams.

Sincerely,



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