February 25, 2020

LivaNova Deutschland GmbH
% Scott Light
Senior Manager, Regulatory Affairs
LivaNova USA, Inc.
14491 West 65th Way
Arvada, Colorado 80004

Re: K191402
Trade/Device Name: Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary Bypass Temperature Controller
Regulatory Class: Class II
Product Code: DWC
Dated: January 17, 2020
Received: January 17, 2020

Dear Scott Light:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel
Assistant Director
Division of Circulatory Support,
Structural and Vascular Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K191402

Device Name

Heater-Cooler System 3T

Indications for Use *(Describe)*

The Heater-Cooler System 3T is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

LivaNova's Heater-Cooler System 3T

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

LivaNova Deutschland GmbH
Lindberghstrasse 25
D-80939 München, Germany

Contact Person:

Bryan Olin, Ph.D.
Senior Vice President, Clinical, Quality, and Regulatory Affairs

Date Prepared: February 20, 2020

Name of Device and Name/Address of Sponsor:

Heater-Cooler System 3T
LivaNova Deutschland GmbH
Lindberghstrasse 25
D-80939 München, Germany

Common or Usual Name:

Cardiopulmonary bypass temperature controller

Classification Name:

21 CFR 870.4250; Product Code DWC

Predicate Device:

Stöckert Heater-Cooler System 3T (K052601)

Intended Use / Indications for Use

The Heater-Cooler 3T System (3T System) is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

Device Description

The 3T System is an independent (*i.e.,* independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one interchangeable heating/cooling circuit for cardioplegia. If required, patient and cardioplegia circuits can be switched off separately, in order to increase the activated functional group's heating and/or cooling performance.

The following optional components and accessories are also available for the 3T System:

1. Heating-cooling blankets;
2. Water circuit tubing; and

3. Various cables.

The 3T System includes a disposable aerosol collection set that consists of a canister connected to the 3T System and the user facility's vacuum source that captures emissions that are drawn from the tank using negative pressure created by the user facility's vacuum.

Technological Characteristics

The technological characteristics of the Final Configuration 3T System are similar to the cleared 3T System (K052601), with a number of minor modifications to the hardware, software and labeling of the device. Both devices employ an independent (i.e., independent of the water supply) heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one interchangeable heating/cooling circuit for cardioplegia. Both devices can also be used with the same types of optional components and accessories, including heating-cooling blankets and various cables and tubing.

Performance Data

The Company conducted performance testing that verified the modifications made to the 3T System reduced the risk of transmission of aerosolized mycobacteria. Testing including the following:

Testing to Verify Reduction in Emission	• Microbiological and orthogonal assay testing during all phases of device operation to evaluate device emissions; • Microbiological testing to verify that the hydrophobic filter of the disposable aerosol collection set's canister adequately prevents contamination of the user facility's vacuum source; and • Microbiological and orthogonal assay testing to verify the seven-day use period of the disposable aerosol collection set.
Aerosol Collection Set Testing	• Testing to verify the chemical resistance of the materials in this disposable Aerosol Collection Set, the integrity and efficacy of the disposable Aerosol Collection Set, and the integrity of the packaging design of the disposable Aerosol Collection Set
Heating and Cooling Testing	• Testing to verify the performance of the heating and cooling functions of the 3T System using a patient simulator circuit.
Corrosion and Erosion Testing	• Testing to evaluate the chemical resistance of the metallic and plastic component and materials of the 3T System.
Cleaning, Disinfection, and Preservation of the Water Circuit	• Validation testing of the cleaning, disinfection, and water preservation instructions provided in the 3T System Operating Instructions per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" demonstrated an intermediate level of disinfection. • Long-term testing (58 weeks) of the cleaning, disinfection, and water preservation instructions verified that the instructions adequately prevent contamination of the device.
Cleaning and Disinfection of 3T System Surfaces	• Validation testing of the 3T System surface cleaning instructions provided in the 3T System Operating Instructions.
Transportation and Storage	• Testing of the transportation and shipping packaging of the 3T System.
Qualification of the Disinfection and Drying	• Process validation testing of the production disinfection and drying processes.

Process used in Production	
Human Factors Testing	• Human factors validation testing of the 3T System Operating Instructions.

Substantial Equivalence

The Final Configuration 3T System has very similar indications for use as the cleared 3T System. In addition, the Final Configuration and cleared 3T Systems have the same fundamental scientific technology, and similar technological characteristics. As explained in the attached 510(k) notice, the minor differences discussed do not raise new or different questions of safety or effectiveness. Furthermore, performance and validation testing demonstrate that the modified 3T System is as safe and effective as the predicate device. Thus, the Company maintains that the Final Configuration 3T System is substantially equivalent to its predicate device.