November 16, 2022

LivaNova Deutschland GmbH
Julia Leslie
Senior Director, Regulatory Affairs CS
Lindbergh Strasse 25
Munchen, BY 80939
Germany

Re: K220635
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: October 12, 2022
Received: October 14, 2022

Dear Julia Leslie:

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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Heater-Cooler System 3T

Indications for Use *(Describe)*

The Heater-Cooler 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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

I. SUBMITTER

Name:	LivaNova Deutschland GmbH
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Date Prepared:	February 28, 2022

II. DEVICE

Proprietary Name:	Heater-Cooler System 3T
Common Name:	Cardiopulmonary bypass temperature controller
Classification Name:	Controller, Temperature, Cardiopulmonary Bypass
Regulation Number:	21 CFR 870.4250
Product Code:	DWC
Device Class:	Class II

III. PREDICATE DEVICE INFORMATION

Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent in function and intended use to **Heater-Cooler System 3T (K191402).**

IV. INDICATIONS FOR USE

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.

V. DEVICE DESCRIPTION

The Heater-Cooler System 3T 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 Heater-Cooler System 3T:

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

The Heater-Cooler System 3T includes a disposable aerosol collection set that consists of a canister connected to the Heater-Cooler System 3T 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.

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The safety of the Heater-Cooler System 3T is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as described in the Operating Manual that was cleared in K191402. The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for the Deep Cleaning service. The Deep Cleaning service is intended to reduce bioburden levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting. There are no changes to design or intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Heater-Cooler System 3T and its predicate have the same intended use, clinical setting, target user, target patient population, and principle of operation.

VII. PERFORMANCE DATA

The following non-clinical testing was performed to support the substantial equivalence of the Heater-Cooler System 3T, with the Deep Cleaning service, to its legally marketed predicate device:

- Process Validation of Deep Cleaning service
  - Installation Qualification
  - Operational Qualification
  - Process Qualification

Animal testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

Clinical testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

VIII. CONCLUSION

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent to its predicate device (K191402).