August 24, 2023

LivaNova Deutschland GmbH
Julie Leslie
Sr. Director, Regulatory Affairs, Cardiopulmonary
Lindberghstr. 25
Munich, 80939
Germany

Re: K232291
Trade/Device Name: Essenz HLM, Essenz IBLM
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ, DRY,
Dated: July 31, 2023
Received: August 1, 2023

Dear Julie 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.

Submission Number *(if known)*

K221373

Device Name

Essenz HLM

Indications for Use *(Describe)*

Essenz HLM is intended to be used during cardiopulmonary bypass for procedures lasting six (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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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
Essenz ILBM

Indications for Use *(Describe)*
Essenz ILBM is indicated for supplementary, in-line monitoring of the extracorporeal arterial oxygen partial pressure, venous oxygen saturation, venous hematocrit/hemoglobin, and arterial and venous temperature during cardiopulmonary bypass procedures up to six hours.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K232291

510(k) Summary

SUBMITTER

Name:	LivaNova Deutschland GmbH
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Date Prepared:	July 31, 2023

DEVICE

Proprietary Name:	**Essenz HLM**
Common Name:	Heart-Lung Machine
Classification Name:	Console, Heart-Lung Machine, Cardiopulmonary Bypass
Classification Panel:	74 Cardiovascular
Regulation Number:	21CFR870.4220
Product Code:	DTQ
Device Class:	Class II

Proprietary Name:	**Essenz ILBM**
Common Name:	Extracorporeal blood-gas monitor
Classification Name:	Cardiopulmonary bypass on-line blood gas monitor
Regulation Number:	21CFR870.4330
Product Code:	DRY
Device Class:	Class II

PREDICATE DEVICE INFORMATION

Essenz HLM is substantially equivalent in function and intended use to its predicate Essenz HLM, K221373, LivaNova Deutschland GmbH.

Essenz ILBM is substantially equivalent in function and intended use to its predicate B-Capta, K202154, LivaNova Deutschland GmbH.

INDICATIONS FOR USE

Essenz HLM is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

Essenz ILBM is indicated for supplementary, in-line monitoring of the extracorporeal arterial oxygen partial pressure, venous oxygen saturation, venous hematocrit/hemoglobin, and arterial and venous temperature during cardiopulmonary bypass procedures up to six (6) hours.

DEVICE DESCRIPTION

Essenz HLM is a modular heart-lung machine. The device consists of a central console base for support, positioning mobility and power supply, roller and centrifugal pumps, user interface displays, controls, clamps and sensors for the monitoring of extracorporeal perfusion.

The Essenz HLM is configurable to user needs with different system components. The main configurable and optional system components consist of:

Console

The Console provides a mobile chassis containing the power supply, several control units and Sensor Interface Modules.

Cockpit

The Essenz HLM Cockpit contains the display and control modules for monitoring, control and measuring devices and is the central user interface between the operator and the Essenz HLM.

Control Units/ Console Control Units

Control and independent supervision of connected pump drive or EVO via local CAN, incl. dual (alternative) actuator management for leftmost CCU.

Pumps

Pumps may be roller or centrifugal pump type. Pumps provide speed-controlled pumping of flow in the ECC (Extra Corporeal Circulation) using a peristaltic

(positive displacement) pump or using a roto-dynamic pump (non-occlusive), automatic clamping and pump control according to measured flow rate and direction

Bubble sensor
Monitoring device that detects air bubbles and microbubbles in the ECC – if detected, a visual and acoustic alarm is triggered, and the pump stops.

Level sensor
The level monitor controls the blood level in the oxygenator/reservoir.
Display, alarm generation and pump speed regulation based on detection of blood level in a venous reservoir within the ECC.

Temperature sensor
The temperature monitor allows the simultaneous measurement and display of up to four temperatures, as measured by connected temperature probes.
Display and alarm generation based on measurement of temperature of flow within the ECC.

Pressure sensor
The pressure sensor module is used to measure and display the pressure in the extracorporeal circuit.
Display, alarm generation and pump speed regulation based on measurement of pressure in the ECC.

Flow Sensor
The flow sensor monitors flow in tubing.
Display, alarm generation and pump regulation based on measurement of flow in the ECC.

Manual Venous Occluder
Provides a separate control unit and line clamp.

Venous Clamp
The clamp closes automatically when the stop link function to the arterial pump is activated. It can be opened or closed manually by the operator via a connected Control Unit.

Arterial Clamp
Clamp arterial line upon centrifugal pump stop / min rpm to fully stop the flow, prevent gravitational backflow in tubing and prevent air delivery to the patient

EP-Pack/ Power Pack
Provide power to system components. Data interface between the system components.

Cabinet (Enclosure)
Data interface between external devices and Data Management System, incl. data encryption

Mast
Provides structural stability and mounting points for system components and disposables

Essenz ILBM is used for in-line continuous monitoring of patient's blood parameters during procedures requiring extracorporeal circulation when used with a compatible heart-lung machine.

Provided in-line measured parameters of Essenz ILBM are:
In the Venous line:

- Haematocrit / Haemoglobin (Hct/Hb)
- Venous blood oxygen saturation (sO_2)
- Venous blood temperature (venT)

In the Arterial line:

- Arterial blood oxygen partial pressure (pO_2)
- Arterial blood temperature (artT)

The duration of application is limited to 6 hours of continuous use.

Essenz ILBM consists of the following components / disposables:

- B-Capta Venous and Arterial Sensors
- Essenz ILBM Sensor Module
- B-Capta Venous and Arterial Reference Element Holders
- B-Capta disposable Venous and Arterial Cuvettes

The B-Capta venous sensor is an optical sensor which measures hematocrit/hemoglobin and oxygen saturation using an optical reflectance technology when connected to its dedicated disposable cuvette. Infrared technology is used to measure the temperature of the venous blood.

The B-Capta arterial sensor is an optical sensor which measures, partial pressure of oxygen using an optical fluorescence technology when connected to its dedicated disposable cuvette. Infrared technology is used to measure the temperature of the arterial blood.

Both sensors are functionally connected to the compatible heart-lung machine. Data are displayed on the graphical user interface of the compatible heart-lung machine.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Essenz HLM and its predicate have the same indications for use, intended use, use environment, intended user, target patient population, principles of operation and technological characteristics. The minor functional differences, including compatibility to LivaNova's Essenz ILBM blood gas monitor and new software and graphical user interface, between the cleared and modified devices do not raise different questions of safety or effectiveness.

Essenz ILBM and its predicate, B-Capta, have the same indications for use, intended use, use environment, intended user, target patient population, principles of operation and technological characteristics.
B-Capta is designed to work integrated with a LivaNova S5 System (K210130). Essenz ILBM, which is a modified B-Capta, is intended to be compatible with LivaNova's Essenz HLM, using the Essenz HLM graphical user interface. The minor differences in interoperability do not raise new issues of safety or effectiveness.

PERFORMANCE DATA – NON-CLINICAL TESTING

No animal testing was submitted to support the substantial equivalence of the Essenz HLM and Essenz ILBM to their predicate devices.

In accordance with 21 CFR 820.30, LivaNova Deutschland GmbH. has conducted the following verification and validation testing of the Essenz HLM and Essenz ILBM to ensure that they can provide all the capabilities necessary to operate safely and effectively:

- Electrical safety
- Electromagnetic compatibility (EMC)
- Performance testing
- Software verification and validation

In support of the determination of substantial equivalence of the Essenz HLM and Essenz ILBM to their predicate devices, the following recognized Standards have been used:

Standard	Title	FDA recognition number
IEC 62304	Medical device software — Software life cycle processes	13-79
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-49
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36
IEC /TR 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-19
IEC 62366-1	Medical devices — Part 1: Application of usability engineering to medical devices	5-129

PERFORMANCE DATA – CLINICAL TESTING

No clinical testing was conducted in support of the Essenz HLM and Essenz ILBM as the technological characteristics and indications for use are equivalent to those of the predicate devices. The non-clinical testing summarized in this submission supports the substantial equivalence of these devices with the respective predicate devices.

SUBSTANTIAL EQUIVALENCE

The Essenz HLM and Essenz ILBM are as safe and effective as the predicate Essenz HLM and B-Capta. Both devices have the same intended use and indications, similar technological characteristics, and the same principles of operation and performance specifications as their predicate devices. The minor technological and functional differences between the cleared and modified devices do not raise different questions of safety or effectiveness.

Performance and validation data demonstrate that the subject Essenz HLM and the subject Essenz ILBM are as safe and effective as the predicate devices. Thus, the Essenz HLM and Essenz ILBM are substantially equivalent to their predicates.