March 9, 2023

LivaNova Deutschland GmbH
Julia Leslie
Senior Director, Regulatory Affairs
Lindberghstr. 25
Munich, Bavaria 80939
Germany

Re: K221373
Trade/Device Name: Essenz HLM
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ, DWA, DWF
Dated: January 18, 2023
Received: January 27, 2023

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,

Rachel E. Neubrander -S

for 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)*
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.

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510(k) SUMMARY

I. SUBMITTER

Name:	LivaNova Deutschland GmbH
Address:	Lindberghstrasse 25 D-80939 München, Germany
Establishment Registration Number	9611109 (Manufacturer: LivaNova Deutschland)
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Date Prepared:	March 3, 2023

II. 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
Secondary Product Codes:	DWA, DWF
Device Class:	Class II

III. PREDICATE DEVICE INFORMATION

Primary predicate:

- **Stöckert S5 System**, Heart-Lung Machine (K210130)

Secondary predicates:

- **Sorin Centrifugal Pump 5 (CP5)** (K112225)
- **Electrical Venous Occluder (EVO)** (K082344)

IV. INDICATIONS FOR USE

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

V. DEVICE DESCRIPTION

Essenz HLM is a modular heart-lung machine like its primary predicate Stöckert S5 System. 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 and several control units.

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.

Electrical venous occluder (EVO)

The clamp closes automatically when the stop link function to the arterial pump is activated.

Arterial Clamp/ Electric Remote Control

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

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

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

- Electrical safety
- Electromagnetic compatibility (EMC)
- Performance testing
- Software verification and validation
- Human Factors testing
- Mechanical testing
- Performance testing of shipping containers

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

Standard	Title	FDA recognition number
IEC 60601-1 2005 A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2 Edition 4.0 2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8
IEC 62366-1 Edition 1.0 2015	Medical devices — Part 1: Application of usability engineering to medical devices	5-114
60601-1-8:2006 and A1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance	5-76

	for alarm systems in medical electrical equipment and medical electrical systems	
IEC 62304 Edition 1.1 2015	Medical device software — Software life cycle processes	13-79
ISO 14971 Third Edition 2019	Application of risk management to medical devices	5-125

CLINICAL TESTING

None required.

ANIMAL TESTING

None required.

VIII. SUBSTANTIAL EQUIVALENCE

The Essenz HLM is as safe and effective as the predicate S5 System. The Essenz HLM has the same intended use and indications, similar technological characteristics, and the same principles of operation as its predicate devices. The minor technological 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 is as safe and effective as the predicate devices.