November 10, 2021

LivaNova Deutschland GmbH
Florian Goetz
Senior Specialist Regulatory Affairs
Lindberghstr. 25
Munich, Bavaria 80939
Germany

Re: K212003
Trade/Device Name: ESSENZ Patient Monitor
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: October 14, 2021
Received: October 15, 2021

Dear Florian Goetz:

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,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212003

Device Name
ESSENZ Patient Monitor

Indications for Use *(Describe)*
ESSENZ Patient Monitor is a modularly structured program package that is exclusively used with LivaNova Heart-Lung Machines. The system allows detailed recording of perfusion data during cardiopulmonary bypass as well as the processing and evaluation of this data. The data may be recorded automatically or entered manually.

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:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 7.0 510(K) SUMMARY

ESSENZ Patient Monitor

## Applicant

**LivaNova Deutschland GmbH**
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| Contact information | |
|---|---|
| **Primary contact person** | **Alternate contact person** |
| Florian Goetz<br>Specialist Regulatory Affairs<br>Florian.Goetz@LivaNova.com | Mattia Ronchetti<br>Director Regulatory Affairs<br>Mattia.Ronchetti@LivaNova.com |

Date Prepared: June 25, 2021

## Application Correspondent

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| Contact information |
|---|
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## Device Information

| | |
|---|---|
| Proprietary Name: | ESSENZ Patient Monitor |
| Common/Usual Name: | Data Management System |
| Classification Name: | Medical cathode-ray tube display |
| Classification Panel: | Cardiovascular |
| Device Class: | Class II |
| Regulation Number: | 21 CFR § 870.2450 |
| Product Code: | DXJ |

## Predicate Device Information

The modified ESSENZ Patient Monitor is substantially equivalent in function and intended use to the Sorin CONNECT cleared in Premarket Notification K170460.

## Indications for Use

The device is a modularly structured program package that is exclusively used with LivaNova/Stockert heart lung machines. The system allows detailed recording of perfusion data during cardiopulmonary bypass as well as the processing and evaluation of this data. The data may be recorded automatically or entered manually.

## Device Description

The ESSENZ Patient Monitor is used to collect and view data generated during cardiopulmonary bypass surgery. It interfaces with LivaNova Heart-Lung machines to capture this data.

The ESSENZ Patient Monitor includes the following main components:

- Software: The data-recording software installed on the Perfusion System Monitor hardware; known as “ESSENZ Patient Monitor”. It is used to save and process the collected data.
- Hardware: The Perfusion System Monitor. It is used to display and transfer the collected data.

- Hardware: A mast holder to mount the Perfusion System Monitor on a vertical mast of the respective LivaNova HLM.

A description of the modules comprising the ESSENZ Patient Monitor is provided below:

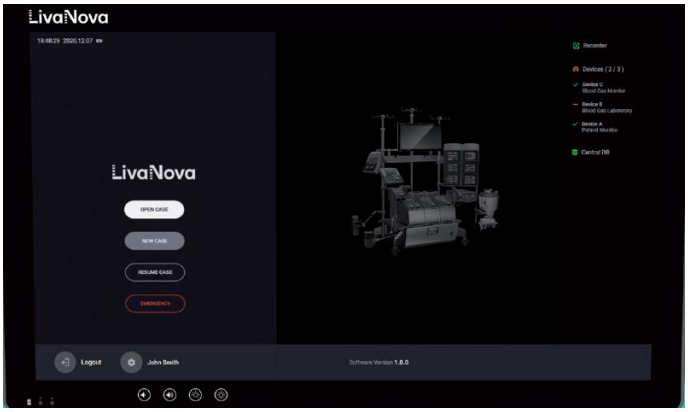
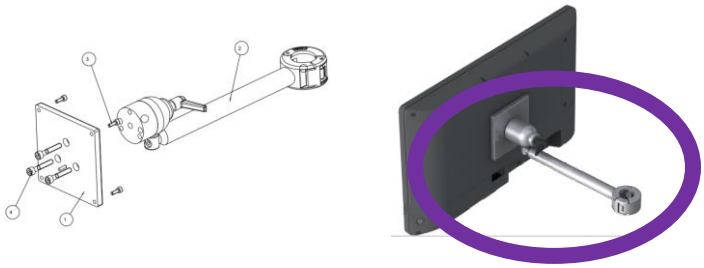
| Component | Description |
|---|---|
| **ESSENZ Patient Monitor Software** | Sample view of Home-screen:<br>  |
| **Perfusion System Monitor** |  <br>ESSENZ Perfusion System Monitor comes complete with an AC/DC power adapter with lockable DC connector. |
| **Perfusion System Monitor holder** |  <br>The mechanical holder allows Perfusion System Monitor to be mounted on a vertical mast of a compatible LivaNova Heart-Lung Machine. |

***Table 7-1:*** *ESSENZ Patient Monitor System components*

## Technological Characteristics

The modified ESSENZ Patient Monitor has the same fundamental technological characteristics, principles of operation, and control mechanisms as the unmodified device. The device modifications are described below.

- Reengineering of the CONNECT legacy software
- Use of a new hardware monitor to replace the CONNECT Datapad
- Adaptation of wording in the indications for use statement to reflect the company name change from "Sorin" to "LivaNova" (the rewording does not affect the substance or meaning of the indications for use)
- Introduction of a new brand name (before: "Sorin CONNECT", after: "Essenz Patient Monitor")

## Performance Data – Non-Clinical Testing

No animal testing was submitted to support the substantial equivalence of the modified device to the cleared Sorin CONNECT.

In accordance with 21 CFR 820.30, LivaNova Deutschland GmbH. has conducted the following verification and validation testing of the ESSENZ Patient Monitor design modifications, using well-established methods, to ensure that it can provide all the capabilities necessary to operate safely and effectively and that unchanged functions of the device continue to operate as intended:

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

In support of the determination of substantial equivalence of the modified device to the cleared Sorin CONNECT, the following recognized Standards have been complied with:

| 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 60601-1-6 Edition 3.2 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | 5-132 |
| IEC 62366-1 Edition 1.0 2015 | Medical devices — Part 1: Application of usability engineering to medical devices | 5-114 |
| 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 |

## Performance Data – Clinical Testing

No clinical testing was conducted in support of ESSENZ Patient Monitor, as the technological characteristics and indications for use are equivalent to those of the predicate device, which has been on the market for several years with proven safety and efficacy of use. The non-clinical testing summarized in this submission supports the substantial equivalence of these devices with the respective predicate device in relation to the changes that are subject of this submission.

## Substantial Equivalence

The modified ESSENZ Patient Monitor is as safe and effective as the cleared Sorin CONNECT. The modified device has the same intended use and indications, similar technological characteristics, and the same principles of operation as its predicate device. The minor technological differences between the cleared and modified device do not raise different questions of safety or effectiveness. Performance and validation data demonstrate that the subject ESSENZ Patient Monitor is as safe and effective as the predicate device. Thus, the modified ESSENZ Patient Monitor is substantially equivalent to its predicate.