July 12, 2021

Sorin Group Italia S.R.L
Luigi Vecchi
Director Regulatory Affairs
Via Statale 12 Nord. 86
Mirandola, Modena 41037
Italy

Re: K211495
Trade/Device Name: EOS PMP
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: June 14, 2021
Received: June 15, 2021

Dear Luigi Vecchi:

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 Gillette
Assistant Director (Acting)
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)*
K211495

Device Name
EOS PMP

Indications for Use *(Describe)*

The EOS PMP hollow fiber oxygenator is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 LPM. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The device is intended to be used for 6 hours or less.

Patient population: Paediatric / small adult

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

(in accordance with 21 CFR 807.92)

510(k) Number:

I. Applicant Information

APPLICANT:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: +39 0535 29957 **e-mail:** luigi.vecchi@livanova.com
APPLICATION CORRESPONDANT:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) ITALY
CONTACT PERSON:	Luigi Vecchi Phone: +39 0535 29957 **e-mail:** luigi.vecchi@livanova.com
DATE PREPARED:	May 7, 2021

II. Subject Devices Identification

PROPRIETARY/ TRADE NAME:	EOS PMP
COMMON/ USUAL NAME:	EOS PMP Hollow Fiber Oxygenator
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator
REGULATION NUMBER:	21 CFR 870.4350
CLASSIFICATION PRODUCT CODE:	DTZ
CLASSIFICATION:	Class II
CLASSIFICATION PANEL;	Cardiovascular

III. Predicate Devices

The **EOS PMP** Hollow Fiber Oxygenator is substantially equivalent to the following cleared predicate devices. All models have the same fundamental scientific technology and intended use

510(k) NUMBER:	K150489
PROPRIETARY/ TRADE NAME:	EOS PMP
COMMON/ USUAL NAME:	EOS PMP Hollow Fiber Oxygenator
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator
REGULATION NUMBER:	21 CFR 870.4350
CLASSIFICATION:	Class II
CLASSIFICATION PANEL;	Cardiovascular

IV. Device Description

The **EOS PMP** Hollow Fiber Oxygenator (hereinafter identified as **EOS PMP**) consist of an oxygenator with an integrated heat exchanger.

The **EOS PMP** consist of the following main components

- a **heat exchanger** consisting of a grooved and pleated stainless steel that is placed into a polycarbonate housing with integrated Hansen connectors and is sealed with resin potting at both ends. it controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery.
- an **oxygenating module** element made of a coiled bundle of polypropylene microporous hollow fibers rolled on the heat exchanger sub assembly. The hollow fiber membrane provides oxygenation and carbon dioxide removal from venous blood or suction blood..

The modified device is a modified version of the currently marketed **EOS** product.

V. Indications for use

The EOS PMP hollow fiber oxygenator is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 LPM. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The device is intended to be used for 6 hours or less.

Note: The intended use of the subject devices is identical to the intended use of the predicate device.

VI. Summary of technical characteristics

The **EOS PMP** subject devices have the same principles of operation and control mechanisms as the **EOS PMP** unmodified device. The **EOS PMP** subject devices and the **EOS PMP** unmodified device share the same fundamental technological characteristics except for some modifications that do not affect the basic device

function. These differences are summarized below and do not raise any new issues of safety and effectiveness.

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1. The **EOS PMP** model with integrated hardshell venous cardiotomy reservoir has been phased out, only the model with oxygenator and heat exchanger will remain on the market;

2. Addition of a coating material (epoxy phenolic primer) to the Heat exchanger stainless steel material;

3. The Instructions for Use were revised to reflect the changes above and improve readability.

No change to the intended use has been made as a result of these modifications. Also, there are no differences in packaging type and material between **EOS PMP** and **EOS PMP** unmodified device. Both modified and unmodified device are for single use only, ethylene oxide sterilized and has a non-pyrogenic fluid path

VII. Substantial equivalence discussion

Based on equivalent intended use and technological characteristics, as well as on equivalent performance testing, the **EOS PMP** can be deemed to be substantially equivalent to its predicate device, the Unmodified **EOS PMP**. The **EOS PMP** as designed and manufactured, does not raise new questions regarding safety and effectiveness as compared to its predicate device and is determined to be substantially equivalent to its predicate device, the Unmodified **EOS PMP**.

VIII. Non clinical performance data

The subject device was tested to ensure that it can provide all the capabilities necessary to operate safely and effectively. Applicable tests were carried out in accordance with the requirements of ISO 10993-1, the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials, and the relevant requirements of "*Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions: Final Guidance for Industry and FDA Staff*" issued on November 13, 2000, and ISO 7199 "*Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)*".
In vitro testing was performed to evaluate the introduction of the coating material in the modified **EOS PMP** version, specifically the following tests were carried on:

- Heat exchanger performance factor verification
- Heat exchanger mechanical integrity
- Flaking/leaching test

This performance testing was conducted on sterile aged devices; accelerated aging for a period of time equivalent to at least 3 years as per device labeling
The modified device successfully met all acceptance criteria for the addition of the new material.

The results of in vitro studies demonstrate that the subject **EOS PMP** performs in a manner substantially equivalent to the Unmodified **EOS PMP** predicate device with respect to the relevant functional parameters.

IX. Clinical performance data

No clinical testing was conducted in support of the **EOS PMP**, as the indications for use are equivalent to those of the predicate, which have been on the market for many years. The non-clinical testing summarized in this submission supports the substantial equivalence of these devices with their respective predicates in relation to the changes subject of this submission.

X. Statement of Substantial Equivalence

As designed and manufactured and based on the intended use, technological characteristics, and performance testing, the modified **EOS PMP** do not raise new questions regarding their safety and effectiveness as compared to their predicates devices and are determined to be substantially equivalent to the predicate devices.