



August 13, 2020

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

Re: K201916

Trade/Device Name: Inspire 6M Hollow Fiber oxygenator, Inspire 7M Hollow Fiber oxygenator,
Inspire 8M Hollow Fiber oxygenator

Regulation Number: 21 CFR 870.4350

Regulation Name: Cardiopulmonary Bypass Oxygenator

Regulatory Class: Class II

Product Code: DTZ, DTR

Dated: July 9, 2020

Received: July 10, 2020

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,

for Fernando Aguel
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

Indications for Use

510(k) Number (if known)
K201916

Device Name

INSPIRE 6M Hollow fiber Oxygenator
INSPIRE 7M Hollow fiber Oxygenator
INSPIRE 8M Hollow fiber Oxygenator

Indications for Use (Describe)

The INSPIRE 6M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass (CPB). It provides gas exchange support and blood temperature control.

The INSPIRE 6M is intended to be used for 6 hours or less.

The INSPIRE 7M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass (CPB). It provides gas exchange support and blood temperature control.

The INSPIRE 7M is intended to be used for 6 hours or less.

The INSPIRE 8M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass (CPB). It provides gas exchange support and blood temperature control.

The INSPIRE 8M is intended to be used for 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
(in accordance with 21 CFR 807.92)

510(k) Number: K201916

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:	July 6, 2020

II. Subject Devices Identification

PROPRIETARY NAME:	INSPIRE 6M Hollow Fiber Oxygenator INSPIRE 7M Hollow Fiber Oxygenator INSPIRE 8M Hollow Fiber Oxygenator
COMMON/ USUAL NAME:	INSPIRE 6M; INSPIRE 7M; INSPIRE 8M.
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator, Cardiopulmonary Bypass Heat Exchanger.
REGULATION NUMBER:	21 CFR 870.4350
PRODUCT CODE:	DTZ, DTR
CLASSIFICATION:	Class II
CLASSIFICATION PANEL;	Cardiovascular

III. Predicate Devices

The **INSPIRE 6M Hollow Fiber Oxygenator, INSPIRE 7M Hollow Fiber Oxygenator and INSPIRE 8M Hollow Fiber Oxygenator** are substantially equivalent to the following cleared predicate devices. All models have the same

fundamental scientific technology and intended use

510(k) NUMBER:	K180448
PROPRIETARY NAME:	INSPIRE 6M Hollow Fiber Oxygenator, INSPIRE 8M Hollow Fiber Oxygenator.
COMMON/ USUAL NAME:	INSPIRE 6M; INSPIRE 8 M.
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator
REGULATION NUMBER:	21 CFR 870.4350
CLASSIFICATION:	Class II
CLASSIFICATION PANEL;	Cardiovascular

510(k) NUMBER:	K190690
PROPRIETARY NAME:	INSPIRE 7M Hollow Fiber Oxygenator
COMMON/ USUAL NAME:	INSPIRE 7M
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator
REGULATION NUMBER:	21 CFR 870.4350
CLASSIFICATION:	Class II
CLASSIFICATION PANEL;	Cardiovascular

IV. Device Description

The **INSPIRE 6M**, **INSPIRE 7M** and **INSPIRE 8M** oxygenators (hereinafter identified as **INSPIRE**) consist of an oxygenator with an integrated heat exchanger.

The **INSPIRE** devices are intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass (CPB). It provides gas exchange support and blood temperature control.

The **INSPIRE** consist of the following main components

- a **heat exchanger** consisting of a bundle of polyurethane hollow fibers that are wound on a cylindrical core. 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 devices are modified versions of the currently marketed **INSPIRE 6M**, **INSPIRE 7M** and **INSPIRE 8M** products.

V. Indications for use

The subject devices (i.e., the **INSPIRE 6M**, **INSPIRE 7M** and **INSPIRE 8M**) are intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. They all provide gas exchange support and blood temperature control. All the devices are 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 respective predicates

VI. Summary of technical characteristics

The INSPIRE subject devices have the same principles of operation and control mechanisms as the **INSPIRE** unmodified device. The **INSPIRE subject devices** and the **INSPIRE** 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.

1. The purge line unidirectional valve present in the recirculation line of the **INSPIRE** devices was changed with another valve from a different supplier, made with different materials and having different performances;
2. A warning in the Instructions for Use was revised to reflect the evidence found during V&V testing.

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 **INSPIRE** and **INSPIRE** 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 **INSPIRE** can be deemed to be substantially equivalent to its predicate device, the Unmodified **INSPIRE**. The **INSPIRE** 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 **INSPIRE**

VIII. Non clinical performance data

The subject devices were tested to ensure that they 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, “*Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA*” issued on November 29, 2000; and ISO 7199 “*Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)*”.

In vitro testing was performed to compare devices with the modified and unmodified purge line unidirectional valve.

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 oxygenating module with the modified purge line unidirectional valve.

successfully met all acceptance criteria for the recirculation line handling.

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

IX. Clinical performance data

No clinical testing was conducted in support of the **INSPIRE**, as the indications for use are equivalent to those of their respective predicates, 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 **INSPIRE** do not raise new questions regarding their safety and effectiveness as compared to their predicate devices and are determined to be substantially equivalent to the predicate devices.