June 12, 2020

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

Re: K200683
Trade/Device Name: INSPIRE 7FM Hollow fiber oxygenator with integrated arterial filter, INSPIRE 7F Hollow fiber oxygenator with integrated arterial filter and hardshell reservoir, INSPIRE 7F DUAL Hollow fiber oxygenator with integrated arterial filter and hardshell reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTM, DTR, DTN, DTP
Dated: May 7, 2020
Received: May 8, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200683

Device Name

INSPIRE 7F M Hollow Fiber Oxygenator with Integrated Arterial Filter

Indications for Use *(Describe)*

The Inspire 7F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control.
The integrated arterial filter provides additional protection against air and solid emboli. The
Inspire 7F M 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.

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200683

Device Name

INSPIRE 7F Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir and Integrated Arterial Filter

Indications for Use *(Describe)*

The Inspire 7F is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass.
It provides gas exchange support and blood temperature control.
The integrated arterial filter provides additional protection against air and solid emboli.
The Inspire 7F 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)

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Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200683

Device Name

INSPIRE 7F Dual Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir and Integrated Arterial Filter

Indications for Use *(Describe)*

The Inspire 7F Dual is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control.
The integrated arterial filter provides additional protection against air and solid emboli. The
Inspire 7F Dual 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.

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Indications for Use

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K200683

I. Applicant Information

Applicant:

SORIN GROUP ITALIA S.R.L.
Via Statale 12 Nord, 86
Mirandola (MO) 41037 Italy

Contact Person:

Luigi Vecchi
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Application Correspondent:

SORIN GROUP ITALIA S.R.L.
Via Statale 12 Nord, 86
Mirandola (MO) 41037 Italy

Contact Person:

Luigi Vecchi
RA Director
Tel: +39-346-391-0707
e-mail: luigi.vecchi@livanova.com

Date Prepared: March 13, 2020

II. Subject Devices Identification

Proprietary Name:	**INSPIRE 7F Hollow Fiber Oxygenator with hardshell/venous cardiotomy reservoir**
Common/Usual Name:	INSPIRE 7F
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ, DTM, DTR, DTN, DTP
Classification:	Class II
Classification Panel:	Cardiovascular

Proprietary Name:	**INSPIRE 7F M Hollow Fiber Oxygenator**
Common/Usual Name:	INSPIRE 7F M
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ, DTM, DTR
Classification:	Class II
Classification Panel:	Cardiovascular

Proprietary Name:	**INSPIRE 7F Dual Hollow Fiber Oxygenator with hardshell/venous cardiotomy reservoir**

Common/Usual Name: INSPIRE 7F Dual
Classification Name: Cardiopulmonary Bypass Oxygenator
Regulation Number: 21 CFR 870.4350
Product Code: DTZ, DTM, DTR, DTN, DTP
Classification: Class II
Classification Panel: Cardiovascular

III. Predicate Devices

The **INSPIRE 7F Hollow Fiber Oxygenator with hardshell/venous cardiotomy reservoir** is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number: **K130433**
Proprietary Name: **INSPIRE 8F Hollow Fiber Oxygenator with hardshell/venous cardiotomy reservoir**
Common/Usual Name: INSPIRE 8F
Classification Name: Cardiopulmonary Bypass Oxygenator
Regulation Number: 21 CFR 870.4350
Classification: Class II
Classification Panel: Cardiovascular

The **INSPIRE 7F M Hollow Fiber Oxygenator** device is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number: **K180448**
Proprietary Name: **INSPIRE 8F M Hollow Fiber Oxygenator**
Common/Usual Name: INSPIRE 8F M
Classification Name: Cardiopulmonary Bypass Oxygenator
Regulation Number: 21 CFR 870.4350
Classification: Class II
Classification Panel: Cardiovascular

The **INSPIRE 7F Dual Hollow Fiber Oxygenator with hardshell/venous cardiotomy reservoir** device is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number: **K122844**
Proprietary Name: **INSPIRE 8F Dual Hollow Fiber Oxygenator with hardshell/venous cardiotomy reservoir**
Common/Usual Name: INSPIRE 8F Dual
Classification Name: Cardiopulmonary Bypass Oxygenator
Regulation Number: 21 CFR 870.4350
Classification: Class II
Classification Panel: Cardiovascular

IV. Devices Description

The **INSPIRE 7F M, INSPIRE 7F and INSPIRE 7F Dual** oxygenators (hereinafter identified as INSPIRE 7F) 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 7F** consist of the following main components:

- a **heat exchanger** consisting of a bundle of polyurethane hollow fibers that are wound on a cylindrical core.
- an **oxygenating module** element made of a coiled bundle of polypropylene microporous hollow fibers rolled on the heat exchanger sub assembly.
- **Hardshell venous/cardiotomy reservoir** to collect, filter, and send venous blood and suction blood to the oxygenator (only models INSPIRE 7F/ 7F DUAL)
- **Arterial filter**: the integrated arterial filter surrounds the oxygenating module and has been designed with a specific geometry that provides protection against air and solid emboli.

The **heat exchanger** consists of a bundle of polyurethane hollow fibers rolled on a cylindrical core. The heat transfer is obtained through the flow of water inside the fibers and the flow of blood outside them. The heat exchanger is inserted in the gas exchanger and surrounded by the **oxygenating module** element, which is constructed of a coiled bundle of polypropylene microporous hollow fibers rolled on the heat exchanger sub assembly. The blood path is around the outside of the fibers, while the gas path is through the lumen of the fibers.

For the versions 7F/ 7F DUAL the oxygenator module is integrated with a **hardshell/venous reservoir** via a molded fitting joint.

The **hardshell/venous reservoir** is comprised of rigid polycarbonate housing. Venous and cardiotomy filtering systems are physically distinct to allow a good filtration efficiency of venous and

suction blood (one filters venous blood, the other filters suction blood).
The reservoir is provided with a vent/vacuum port together with an over- under‖ valve, that prevents excess of negative or positive pressure avoiding implosion and over pressurization of the reservoir itself. The blood enters the reservoir through the cardiotomy section through the rotating turret equipped with 3/8‖, 1/4‖ and female luer inlet connectors and through the venous inlet 1/2‖ connector provided with female luer connector. Both cardiotomy turret and venous inlet connectors can rotate 360°. The reservoir lid also has additional unfiltered luer ports

The **integrated arterial filter** has a toroidal shape and a 38 µm linear filter screen. It is molded to the shell of the oxygenator. It has been designed with a specific geometry that provides protection against air and solid emboli. The arterial filter has a two-compartment design, including pre- and post- filter chambers. Each one of the two compartments is provided with a dedicated purge site that enhances air purging. The pre-filter chamber removes air bubbles trapped by the filter screen. The post-filter collection chamber is located at the top of the filter and allows air bubble collection of the air dragged through the filter screen. In case of massive air embolism, the air bubbles can be removed through the purge sites located both in the pre- and post- filter collection chamber

The **oxygenating module** of all the INSPIRE oxygenators include a dedicated outlet with a one-way valve that provides access to arterial blood throughout the procedure for cardioplegia, perfusion or blood concentration. The outlet is placed close to the arterial outlet of the oxygenator and opposite to the temperature probe port. Arterial and venous temperature probe sites are also provided: the former is located close to the arterial blood outlet, while the latter is placed on the venous inlet of the reservoir. **Figure 1** shows the oxygenating modules with the visible ports identified.

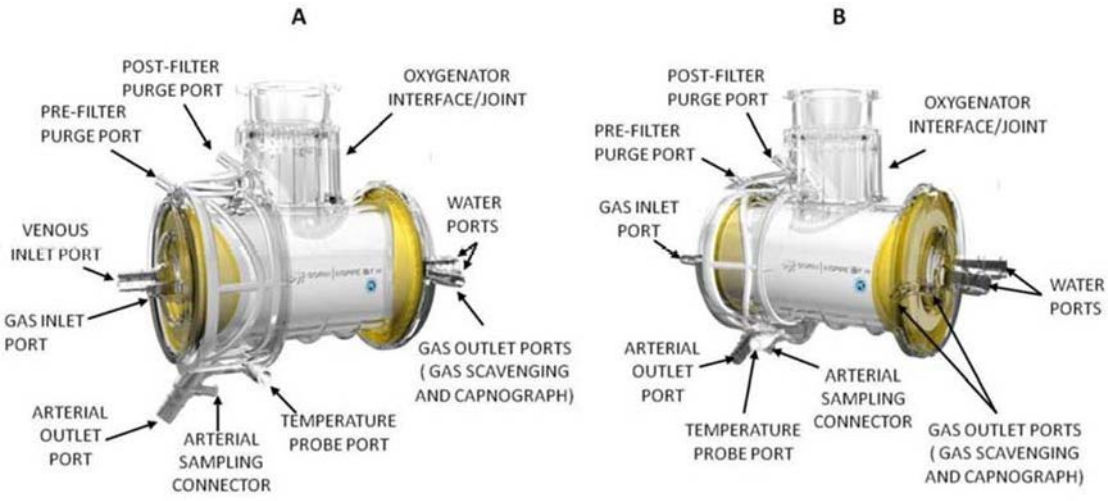

Figure 1: Oxygenating module integrated with heat exchanger and Arterial filter

The respective predicates devices Inspire 8F M, Inspire 8F and Inspire 8F Dual have the same main components of the three subject devices. CPB circuits mimic and temporarily replace the function of the heart and lungs while the heart is arrested to provide a bloodless and stable surgical field, while maintaining physiological support to the rest of the body in which venous blood is drained to a reservoir, oxygenated and sent back to the body through a pump.
The clinical need for the devices under evaluation is to provide a safe and well- functioning alternative to the patient circulation for the entire duration of a cardiopulmonary bypass procedure. The devices can be used to temporarily support pulmonary function of a patient immediately after a Cardiac surgery Operation within the maximum time allowed of 6 hours.

An overview of functional and performance characteristics of Inspire 7F is summarized in Table 1 below.

Table 1. Inspire 7F Performance Characteristics

CHARACTERISTICS	INSPIRE 7F
Maximum recommended blood flow	**7.0 l/min**
Minimum recommended blood flow	**2.0 l/min**

Minimum blood flow (up to 2 hours max. duration time)		**0.5 l/min**
Maximum suggested gas/blood flow ratio		**2 :1**
Blood path pressure drop *(Hb 12 g/dl and temperature 37°C)*		**@Qb=6 LPM** *174 mmHg* *(23.2 KPa /0.23 bar/3,4 psi)*
Heat exchange performance factor (Qw = 11.5 □ 0.2 l/min)		(at Qb = 6 l/min) **0.59**
Integrated Arterial filter: Filtration Efficiency		**100%**
Maximum operating pressure	*Blood path*	**750 mm Hg** *(100 kPa/ 1 bar / 14.5 psi*
	Water path	**1500 mm Hg** *(200 kPa/ 2 bar / 29 PSI*
GAS MODULE + HEAT EXCHANGER	*Priming volume* *Residual volume*	**366 ml** **169 ml**
GAS EXCHANGE MEMBRANE	*Fiber surface*	**1.78 m^2**
HEAT EXCHANGE MEMBRANE	*Fiber surface*	**0.4 m^2**
INTEGRATED ARTERIAL FILTER	*Filtering surface* *Type*	**0.0097** **Polyester screen 38 µm**

V. Indications for Use

The three subject devices (i.e., the **INSPIRE 7F Hollow Fiber Oxygenator with integrated hard shell venous/cardiotomy reservoir**, the **INSPIRE 7F M Hollow Fiber Oxygenator** and the **INSPIRE 7F Dual Hollow Fiber Oxygenator with integrated hard shell venous/cardiotomy reservoir**), – are intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. They all provide gas exchange support and blood temperature control. The integrated arterial filter provides additional protection against air and solid emboli. All the devices

are intended to be used for 6 hours or less.
Note: The intended use of the three subject devices is identical to the intended use of the three respective predicates devices

VI. Summary of Technical Characteristics

The **INSPIRE 7F** has the same principles of operation and control mechanisms as the **INSPIRE 8F** unmodified device.
The **INSPIRE 7F** and the **INSPIRE 8F** 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. The density of the hollow fiber in the oxygenating bundle has been decreased from 16.3 to 15.3
The diameter of the oxygenator bundle has been increased from 82.9 -85.6 mm to 85.1-86.4 mm. The diameter of the oxygenating body has been increased from 83.85 mm to 84.41 mm (max)
No change to the intended use has been made as a result of these modifications.
No different materials were introduced / changed as a result of these modifications.
There are no differences in packaging type and material between **INSPIRE 7F** and **INSPIRE 8F** 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 7F** can be deemed to be substantially equivalent to its predicate device, the Unmodified INSPIRE 8F
The **INSPIRE 7F** 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 8F**.

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 carried out to demonstrate both the substantial equivalence with the predicate device and also to comply with safety and effectiveness requirements.

Testing includes performance tests and physical/mechanical integrity tests that demonstrate compliance with performance specifications.

The INSPIRE 7F met all acceptance criteria for each of the tests listed in the table below.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Physical/Mechanical	Oxygenating module structural integrity
2	Physical/Mechanical	Oxygenating module blood, water, gas pathway integrity
3	Functional/Performance	Oxygenating module blood volume capacity
4	Functional/Performance	Oxygenating module heat exchange performance/water side pressure drop
5	Functional/Performance	Oxygenating module gas transfer performance/blood side pressure drop
6	Functional/Performance	Oxygenating module air handling capability
7	Functional/Performance	Oxygenating module filtration efficiency
8	Functional/Performance	Oxygenating module blood trauma (hemolysis and blood compatibility)
9	Functional/Performance	Oxygenating module leaching of coating

10	Functional/Performance	Integrated device flaking of coating
11	Functional/Performance	Oxygenating module uniformity of coating
12	Functional/Performance	Flow rate capacity

The results of in vitro studies demonstrate that the INSPIRE 7F performs in a manner substantially equivalent to the INSPIRE 8F predicate device with respect to the relevant functional parameters.

IX. Clinical Performance Data

No clinical testing was conducted in support of the **INSPIRE 7F Hollow Fiber Oxygenator with integrated hardshell venous/cardiotomy reservoir r**, the **INSPIRE 7F M Hollow Fiber Oxygenator** and the **INSPIRE 7F Dual Hollow Fiber Oxygenator with integrated hardshell venous/cardiotomy reservoir**, 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 **INSPIRE 7F Hollow Fiber Oxygenator with integrated hardshell venous/cardiotomy reservoir**, the **INSPIRE 7F M Hollow Fiber Oxygenator** and the **INSPIRE 7F Dual Hollow Fiber Oxygenator with integrated hardshell venous/cardiotomy reservoir** 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.