December 22, 2025

Sorin Group Italia S.r.l.
Martina Carlini
Regulatory Affairs Specialist
Via Statale 12 Nord, 86
Mirandola (Modena), IT 41037
Italy

Re: K251783
Trade/Device Name: Inspire HCR and HCR DUAL cardiotomy reservoirs
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: November 28, 2025
Received: November 28, 2025

Dear Martina Carlini:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 M. Gillette -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251783

Device Name
Inspire HCR and Inspire HCR Dual cardiotomy reservoirs

Indications for Use *(Describe)*
The Inspire HCR and Inspire HCR DUAL cardiotomy reservoir are a device allowing suction blood recovery during extracorporeal circulation procedures, by providing blood collection and storage.
In addition, the device supports extracorporeal system priming and defoams and filters suctioned blood. The Inspire HCR must be used up to 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.

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number:

I. Applicant Information

Applicant:

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

Contact Person:

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Application Correspondent:

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Date Prepared: **December 19th 2025**

II. Subject Device Identification

Device Trade Name:	Inspire HCR and Inspire HCR DUAL cardiotomy reservoirs
Classification Name:	Cardiopulmonary bypass blood reservoir
Regulation Number:	21 CFR 870.4400
Product Code:	DTN
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Device

The *Inspire HCR and Inspire HCR DUAL cardiotomy reservoirs* are substantially equivalent to the following cleared predicate devices. Both modified and unmodified models have the same fundamental scientific technology and intended use:

INSPIRE HVR	510(k) Number:	K130433
	Device Trade Name:	INSPIRE 8 HOLLOW FIBER OXYGENATOR WITH INTEGRATED HARDSHELL RESERVOIR, INSPIRE 8F HOLLOW FIBER OXYGENATOR WITH INTEGRATE
	Classification Name:	Oxygenator, Cardiopulmonary Bypass
	Regulation Number:	21 CFR 870.4350
	Product Code:	DTZ
	Classification:	Class II
	Classification Panel:	Cardiovascular
INSPIRE HVR DUAL	510(k) Number:	K122844
	Device Trade Name:	INSPIRE 8F DUAL HOLLOW FIBER OXYGENATOR WITH INTEGRATED ARTERIAL FILTER AND HARDSHELL RESERVOIR
	Classification Name:	Oxygenator, Cardiopulmonary Bypass
	Regulation Number:	21 CFR 870.4350
	Product Code:	DTZ
	Classification:	Class II
	Classification Panel:	Cardiovascular

IV. Device Description

The Inspire HCR and Inspire HCR DUAL cardiotomy reservoirs are single-use, non-toxic, non-pyrogenic and supplied sterile in individual packs.
They are made by clear rigid shell reservoir (hard shell reservoirs), with suction/vent inlet and accessory connectors on the lid, and outlet connector on the bottom. These devices integrate a defoaming body, a filter, and a storage capacity function.
They are devices allowing suction blood recovery during extracorporeal circulation procedures, by providing blood collection and storage. In addition, they support extracorporeal system priming, they defoam and filter suctioned blood. These cardiotomy reservoirs must be used up to 6 hours or less.

The *Inspire HCR and Inspire HCR DUAL cardiotomy reservoir* are the modified version of the hard-shell reservoirs of the Inspire 8 and 8F hollow fiber oxygenator with integrated hardshell reservoir (Inspire HVR) (K130433) and the Inspire 8F dual hollow fiber oxygenator with integrated arterial filter and dual chamber hardshell venous/cardiotomy reservoir (Inspire HVR DUAL) (K122844).

V. Indications for Use

The Inspire HCR/HCR DUAL cardiotomy reservoir is a device allowing suction blood recovery during extracorporeal circulation procedures, by providing blood collection and storage.
In addition, the device supports extracorporeal system priming and defoams and filters suctioned blood. The Inspire HCR/HCR DUAL must be used up to 6 hours or less.

VI. Summary of Technical Characteristics

The Inspire HCR and Inspire HCR DUAL cardiotomy reservoir have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices except for the absence, in the modified devices, of the venous blood filtering components (venous return connector, venous return filter).
The hot melt glue material used to close the polyurethane toroids of cardiotomy filter and to seal the cardiotomy filter base consisting of polyurethane toroid, filter net and filter base, in both Inspire HCR and HCR DUAL cardiotomy reservoirs, has been changed with another one.
Then, the PP material of the conveyor in the Non-Activated blood section of the Inspire HCR DUAL cardiotomy reservoir has been changed with another PP material.
The devices are ethylene oxide sterilized and have a non-pyrogenic fluid path. They are for single use only.

VII. Non-Clinical Performance Data

Sorin Group Italia S.r.l. has conducted extensive verification and validation testing of the Inspire HCR and Inspire HCR DUAL cardiotomy reservoir, as disposables used to allow suction blood recovery during extracorporeal circulation procedures, by providing blood collection and storage and used to support extracorporeal system priming and defoams and filters suctioned blood.
In detail the following testing were performed:

- Blood trauma
- Pressure integrity (blood pathway integrity)
- Pressure drop
- Leak (structural integrity of connectors)
- Defoaming / Maximum operating volumes
- Flow rate capacity

The Inspire HCR and Inspire HCR DUAL cardiotomy reservoirs comply with all the applicable voluntary standards related to cardiovascular systems. The devices passed all the testing in accordance with national and international standards.

VIII. Clinical Performance Data

No clinical testing was conducted in support of the Inspire HCR and HCR DUAL cardiotomy reservoirs, as the indications for use and technical characteristics are equivalent to those of the predicate devices (except for the absence, in the modified devices, of the venous blood filtering components - venous return connector, venous return filter), which have 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 the subject devices with the predicate devices when used according to their intended use.

IX. Statement of Substantial Equivalence

Based on equivalent intended use and technological characteristics, as well as on equivalent performance testing, the Inspire HCR and Inspire HCR DUAL cardiotomy reservoirs can be deemed to be substantially equivalent to their predicate devices:

- the unmodified hard-shell reservoir, Inspire HVR, of the Inspire 8 and 8F hollow fiber oxygenator with integrated hardshell reservoir, cleared under K130433;
- the unmodified hard-shell reservoir, Inspire HVR DUAL, of the Inspire 8F dual hollow fiber oxygenator with integrated arterial filter and dual chamber hardshell venous/cardiotomy reservoir, cleared under K122844;

The Inspire HCR and Inspire HCR DUAL cardiotomy reservoirs, as designed and manufactured, do not raise new questions regarding safety and effectiveness as compared to their predicate devices and are determined to be substantially equivalent to their predicate devices listed above.