January 30, 2026

Sorin Group Italia S.R.L.
Luigi Vecchi
Director RA
Via Statale 12 Nord, 86
Mirandola, MO 41037
Italy

Re: K253671
Trade/Device Name: Dual Stage Venous Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: October 19, 2025
Received: November 21, 2025

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 (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,

Meaghan Erlewein -S

For 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)*
K253671

Device Name
Dual Stage Venous Return Cannulae

Indications for Use *(Describe)*
The Dual Stage Venous Return Cannula is indicated for single tube venous drainage from the right atrium and vena cava during cardiopulmonary bypass surgery for up to six hours.

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.

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K253671

I. Applicant Information

Applicant:

SORIN GROUP ITALIA S.R.L.
Via Statale 12 Nord, 86
Mirandola, MO 41047 Italy

Contact Person: **Luigi Vecchi**
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Application Correspondent:

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Contact Person: **Luigi Vecchi**
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Date Prepared: **January 23th 2026**

II. Subject Device Identification

Device Trade Name:	Dual Stage Venous Return Cannulae
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Device

The Dual Stage Venous Return Cannulae are substantially equivalent to the following cleared predicate device. Both modified and unmodified models have the same fundamental scientific technology and intended use:

Venous cannulae	510(k) Number:	K943934
	Device Trade Name:	Venous Cannulae
	Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
	Regulation Number:	21 CFR 870.4210
	Product Code:	DWF
	Classification:	Class II
	Classification Panel:	Cardiovascular

IV. Device Description

Dual Stage Venous Return Cannulae are single-use, non-toxic, non-pyrogenic fluid path devices and supplied sterile and individually packaged.

The devices are composed of the cannula: an open lumen PVC polymer tube incorporating wire reinforcement in distal section. In some models is present a malleable obturator inserted into the cannula to allow the placement of the cannula along the vein. Once the cannula is positioned onto the vessel the surgeon removes the obturator from the cannula tubing and connects it to the venous line.

The distal end of the cannula has a lighthouse-shaped tip, allowing the venous blood to flow from the vessel into the cannula, in addition the distal sections of the cannula are perforated with multiple holes at multiple stages to better allow the fluid flows from outside into the cannula body. The clear proximal section is not reinforced to allow clamping; the proximal end typically does not have any pre-mounted connector and can accommodate a barbed connector for standard cardiopulmonary bypass tubing (½" diameter). In some models a pre-mounted 1/2" barbed connector is present.

The following cannula models are available:

Device trade name	Model	French size (Outside diameter)	Characteristics
Dual Stage Venous Cannulae	RDS-61040	Proximal: 40 Fr Distal: 32 Fr.	Without connector
Dual Stage Venous Cannulae	RDS-61034	Proximal: 46 Fr Distal: 34 Fr.	Without connector
Dual Stage Venous Cannulae	RDS-61046	Proximal: 46 Fr Distal: 36 Fr.	Without connector
Dual Stage Venous Cannulae	RDS-61050	Proximal: 50 Fr Distal: 36 Fr.	Without connector
Dual Stage Venous Cannulae	RDS-61140	Proximal: 40 Fr Distal: 32 Fr.	With connector
Dual Stage Venous Cannulae	RDS-61134	Proximal: 46 Fr Distal: 34 Fr.	With connector
Dual Stage Venous Cannulae	RDS-61146	Proximal: 46 Fr Distal: 36 Fr.	With connector
Dual Stage Venous Cannulae	RDS-61150	Proximal: 50 Fr Distal: 36 Fr.	With connector

The Dual Stage Venous Return Cannulae are the modified version of the disposables currently marketed under K943934.

Both modified and unmodified cannulae models are recommended for use as Venous cannula during cardiopulmonary bypass up to six hours.

V. Indications for Use

The Dual Stage Venous Return Cannula is indicated for single tube venous drainage from the right atrium and vena cava during cardiopulmonary bypass surgery for up to six hours.

VI. Summary of Technical Characteristics

The Dual Stage Venous Return Cannulae have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices.
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 Dual Stage Venous Return Cannulae; specifically, the following tests were carried out according to standard ISO 18193 ed. 2021:

- Visual inspection
- Connector testing 180° pull test
- Cannula clamp test
- Blood pathway integrity
- Flow rate and pressure drop through cannulae
- Cannula kink test
- Label legibility
- Drainage cannula collapse resistance
- Cannula integrity
- Pull strength
- Blood trauma characterization test
- Biocompatibility

The devices passed all the testing in accordance with standards.

VIII. Clinical Performance Data

No clinical testing was conducted in support of the Dual Stage Venous Return Cannulae, the indications for use and technical characteristics are equivalent to those of the predicate devices, 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 the Dual Stage Venous Return Cannulae can be deemed to be substantially equivalent to their predicate devices:

- the unmodified Venous cannulae, cleared under K943934;

The Dual Stage Venous Return Cannulae, 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.