March 11, 2026

LivaNova USA Inc
% Martina Carlini
RA Specialist
Sorin Group Italia S.r.l.
86, Via statale 12 Nord
Mirandola, IT 41037
Italy

Re: K250937
Trade/Device Name: Venous Return Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: February 4, 2026
Received: February 4, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250937 ?

Please provide the device trade name(s). ?

Venous Return Cannulae

Please provide your Indications for Use below. ?

The Venous Return Cannula is indicated for use in drainage of the superior and inferior vena cava during cardiopulmonary bypass surgery for up to six hours.

Please select the types of uses (select one or both, as applicable). ?

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K250937

I. Applicant Information

Applicant:

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

Contact Person: **Luigi Vecchi**
Regulatory Affairs Director
Tel: +39 0535 29957
e-mail: luigi.vecchi@livanova.com

Date Prepared: **January 27th 2026**

II. Subject Device Identification

Device Trade Name: 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 Devices

The *Venous Return Cannulae* are substantially equivalent to the following cleared predicate devices. Both subject and predicate devices have the same fundamental scientific technology and intended use:

Venous cannulae	510(k) Number:	K943934
	Device Trade Name:	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

Venous cannulae	510(k) Number:	K890980
	Device Trade Name:	Modified Stockert_Shiley Venous Catheter
	Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
	Regulation Number:	21 CFR 870.4210
	Product Code:	DWF
	Classification:	Class II
	Classification Panel:	Cardiovascular

Venous cannulae	510(k) Number:	K861496
	Device Trade Name:	Stockert_Shiley Venous Catheter
	Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
	Regulation Number:	21 CFR 870.4210
	Product Code:	DWF
	Classification:	Class II
	Classification Panel:	Cardiovascular

Venous cannulae	510(k) Number:	K994209
	Device Trade Name:	Stockert V142 Series 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

Venous cannulae	510(k) Number:	K120988
	Device Trade Name:	DLP Single stage venous cannula DLP Right angle single stage venous cannula
	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

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

The devices are composed of the cannula: an open lumen PVC polymer tube incorporating wire reinforcement in distal section.

The distal end of the cannula has a lighthouse-shaped tip, allowing the venous blood to flow from the vessel into the cannula. 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 (¼"; ½" or 3/8" diameter).

The following cannula models are available:

Model	Catalog N°	French size (Outside diameter)	Effective working length
Venous Single stage with straight tip	RV-40016	16 French	12.0 inch (30.5 cm)
	RV-40018	18 French	14.0 inch (35.5 cm)
	RV-40020	20 French	14.0 inch (35.5 cm)
	RV-40022	22 French	14.0 inch (35.5 cm)
	RV-40024	24 French	14.0 inch (35.5 cm)
	RV-40026	26 French	16.0 inch (40.6 cm)
	RV-40028	28 French	16.0 inch (40.6 cm)
	RV-40030	30 French	16.0 inch (40.6 cm)
	RV-40032	32 French	16.0 inch (40.6 cm)
	RV-40034	43 French	16.0 inch (40.6 cm)
	RV-40036	36 French	16.0 inch (40.6 cm)

Model	Catalog N°	French size (Outside diameter)	Tip length
Venous Single stage with right angle tip	RV-41018	18 French	1.2 inch (3.0 cm)
	RV-41020	20 French	1.4 inch (3.5 cm)
	RV-41022	22 French	1.4 inch (3.5 cm)
	RV-41024	24 French	1.6 inch (4.0 cm)
	RV-41026	26 French	1.6 inch (4.0 cm)
	RV-41028	28 French	1.6 inch (4.0 cm)
	RV-41030	30 French	2.2 inch (5.5 cm)
	RV-41032	32 French	2.2 inch (5.5 cm)
	RV-41034	43 French	2.2 inch (5.5 cm)
	RV-41036	36 French	2.4 inch (6.0 cm)

V. Indications for Use

The Venous Return Cannula is indicated for use in drainage of the superior and inferior vena cava during cardiopulmonary bypass surgery for up to six hours.

VI. Summary of Technical Characteristics

The Venous Return Cannulae have the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate devices.

The PVC material in the body and tip of the Venous cannulae was changed with another PVC material in order remove the phthalates (DEHP and DnHP) used as plasticizers currently present in the device.

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 Venous Return Cannulae; specifically, the following tests in accordance with ISO 18193 were carried out:

- 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

VIII. Clinical Performance Data

No clinical testing was conducted in support of the 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 characteristics the Venous Return Cannulae can be deemed to be substantially equivalent to their predicate devices:

- the unmodified Venous Return Cannulae, cleared under K943934
- the Modified Stockert-Shiley Venous Catheter, cleared under K890980
- the Stockert-Shiley Venous Catheter, cleared under K861496
- the Stockert V142 Series Venous Cannulae cleared under K994209
- the Medtronic DLP Single stage venous cannula and DLP Right angle single stage venous cannula cleared under K120988

The 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.