



September 28, 2026

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

Re: K262052

Trade/Device Name: Tri 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: August 26, 2026
Received: August 26, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

**KATHLEEN M.
GRUNDER-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.

K262052

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Please provide the device trade name(s).

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Tri Stage Venous Cannulae

Please provide your Indications for Use below.

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

The proposed patient population is Adults and Adolescents.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K262052

I. Applicant Information

Applicant:

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

Contact Person:

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Application Correspondent:

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Contact Person:

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Date Prepared:

September 23, 2026

II. Subject Device Identification

Device Trade Name: Tri Stage 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

III. Predicate Device

The Tri Stage Venous cannulae are substantially equivalent to the following cleared predicate devices. Both subject and predicate devices have the same fundamental scientific technology and intended use:

Primary Predicate Device

Venous cannulae	510(k) Number:	K251258
	Device Trade Name:	MC2X Three-stage 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

Secondary Predicate Device

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

IV. Device Description

Tri Stage Venous 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. A malleable obturator is 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 the cannula 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 to flow 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 (1/2" or 3/8" diameter). In some models a pre-mounted 1/2" or 3/8" barbed connector is present.

The following cannula models are available:

Device trade name	Model	French size (Outside diameter)	Characteristics
Tri stage Venous cannula	RTS-11029	Proximal 1: 29 Fr Proximal 2: 29 Fr Distal: 29 Fr	without connector
Tri stage Venous cannula	RTS-11129	Proximal 1: 29 Fr Proximal 2: 29 Fr Distal: 29 Fr	with connector
Tri stage Venous cannula	RTS-13029	Proximal 1: 29 Fr Proximal 2: 37 Fr Distal: 37 Fr	without connector
Tri stage Venous cannula	RTS-13129	Proximal 1: 29 Fr Proximal 2: 37 Fr Distal: 37 Fr	with connector

V. Indications for Use

The Tri Stage Venous Cannula is indicated for single tube venous drainage from the right atrium and vena cava during cardiopulmonary bypass surgery for up to six hours. The patient population is Adults and Adolescents.

VI. Summary of Technical Characteristics

The Tri Stage Venous cannulae have the same fundamental technological characteristics, principles of operation and control mechanisms as the MC2X and Venous Return Cannulae predicate devices.

Both subject and predicate devices are recommended for use as Venous cannulae during cardiopulmonary bypass up to six hours.

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 Tri stage Venous cannulae; specifically, the following tests in accordance with ISO18193 were carried out:

TEST CLASSIFICATION	TEST DESCRIPTION
Verification/Validation	Visual Inspection
Verification/Validation	Label legibility and marking durability
Verification/Validation	Cannula kink test
Verification/Validation	Cannula Integrity
Verification/Validation	Pull strength
Verification/Validation	Blood pathway integrity
Verification/Validation	Flow rate and pressure drop through cannulae
Verification/Validation	Drainage cannula collapse resistance
Verification/Validation	Blood trauma characterization test
Biocompatibility	Cytotoxicity
Biocompatibility	Intracutaneous reactivity
Biocompatibility	Sensitization
Biocompatibility	Systemic Toxicity
Biocompatibility	Pyrogenicity (material mediated)
Biocompatibility	Hemocompatibility (Hemolysis, Coagulation, Complement activation, Platelet and Leukocyte count assay)
Biocompatibility	Genotoxicity (Mutation Assay, Mouse lymphoma)

The devices passed all the testing in accordance with the above-mentioned standard.

VIII. Clinical Performance Data

No clinical testing was conducted in support of the Tri stage Venous cannulae, the indications for use and technical characteristics are equivalent to those of the predicate devices. 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 Tri Stage Venous cannulae can be deemed to be substantially equivalent to the following predicate devices:

- Medtronic MC2x Three-stage venous cannulae cleared under K251258
- Venous Return Cannulae, cleared under K943934

The Tri Stage Venous Cannulae, as designed and manufactured, do not raise new questions regarding safety and effectiveness as compared to the predicate devices and are determined to be substantially equivalent to the predicate devices.