February 22, 2024

Sorin Group Italia s.r.l.
Luigi Vecchi
Director Regulatory Affairs
Via Statale 12 Nord, 86
Mirandola (Modena), 41037
Italy

Re: K240193
Trade/Device Name: R501 - R502 aortic root cannulae with and without vent line (R501-15: R501-20: R501-26. R502-15; R502-20: R502-26)
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: January 24, 2024
Received: January 24, 2024

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.

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,

Eric E. Richardson -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.

Submission Number *(if known)*

K240193

Device Name

R501 - R502 aortic root cannulae with and without vent line (R501-15: R501-20: R501-26. R502-15; R502-20: R502-26)

Indications for Use *(Describe)*

The Aortic root cannulae are intended for use in adult and pediatric patients to cannulate the aortic root for cardioplegic solution delivery into the coronary arteries and for venting of the heart during cardiopulmonary bypass surgery for periods of 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.

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K240193

I. Applicant Information

Applicant:

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Date Prepared: **February 22th 2024**

II. Subject Device Identification

Proprietary Name:	R501 – R502 aortic root cannulae with and without vent line (R501-15; R501-20; R501-26; R502-15; R502-20; R502-26)
Common/Usual Name:	Cardiopulmonary bypass vascular 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

III. Predicate Device

The R501-R502 Aortic Root Cannula is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	K200612
Proprietary Name:	R501 Aortic Root Cannula without vent line R502 Aortic Root Cannula with vent line
Common/Usual Name:	Cardiopulmonary bypass vascular 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

The R501-R502 Aortic Root Cannula (hereinafter referred to as R501-R502 cannulae) are aortic root cannulae intended to be used to cannulate the aortic root, to vent and to deliver cardioplegic solution during heat bypass operations.

The device is available in two styles: with a vent line (R502) and without a vent line (R501). Both models consist of a flexible Polyvinylchloride (PVC) tubing body, a PVC flanged tip and luer connector. The introducer is made of stainless steel with a PVC obturator. The vent line model have an additional feature constituted by a vent line provided as integral part of the device. This attribute makes it possible to vent and also introduce cardioplegic solutions using the same device. These cannulae are available in a range of sizes as per table below:

Model	Tip size (internal diameter)	Product designation
R501 (aortic root without vent line)	1.5 mm	R501-15
	2.0 mm	R501-20
	2.6 mm	R501-26
R502 (aortic root with vent line)	1.5 mm	R502-15
	2.0 mm	R502-20
	2.6 mm	R502-26

The R501-R502 cannulae are a modified version of the currently marketed R501-R502 Aortic Root cannulae (K200612).

V. Indications for Use

The Aortic root cannulae are intended for use in adult and pediatric patients to cannulate the aortic root for cardioplegic solution delivery into the coronary arteries and for venting of the heart during cardiopulmonary bypass surgery for periods of up to six hours.

VI. Summary of Technical Characteristics

The R501-R502 Cannulae have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices.

The R501-R502 Cannulae are provided with a different material for some component of the device (Handle, Obturator, Luer connector and Three ways connector): the PVC material used for these component in the R501-R502 Cannulae is without Dioctyltinbis(2-ethyhexylthioglycolate (DOTE) while the original PVC material used in the unmodified devices does contain DOTE.

No other design changes have been made to the device. Except for the change of the PVC material, the R501-R502 cannulae utilize the same materials as the unmodified cannulae.

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 R501-R502 Cannulae, as a cardiopulmonary bypass arterial cannula capable of providing adequate perfusion to the patient during surgery. The R501-R502 Cannulae complies with all the applicable voluntary standards related to cardiopulmonary bypass arterial cannulae. The device passed all the testing in accordance with national and international standards.

VIII. Clinical Performance Data

No clinical testing was conducted in support of the R501-R502 Cannulae, as the indications for use and technical characteristics are equivalent to those of the predicate device, which has 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 device with the predicate device when used according to its intended use.

IX. Statement of Substantial Equivalence

Based on equivalent intended use and technological characteristics, as well as on equivalent performance testing, the R501-R502 Cannulae can be deemed to be substantially equivalent to its predicate device, the Unmodified R501-R502 Cannulae, cleared under K200612.

The R501-R502 Cannulae, 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 R501-R502 Cannulae.