May 30, 2025

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

Re: K250150
Trade/Device Name: VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set); VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set with shunt); VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood Cardioplegia Set Mini)
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary bypass heat exchanger
Regulatory Class: Class II
Product Code: DTR
Dated: January 18, 2025
Received: January 21, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250150

Device Name
VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set);
VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set with shunt);
VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood Cardioplegia Set Mini)

Indications for Use *(Describe)*
Vanguard 4:1 Blood cardioplegia sets are cardiopulmonary bypass devices allowing cardioplegia fluid delivery. They also regulate cardioplegia fluid temperature and trap air emboli. The devices are intended to be used for 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.

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: K250150

I. Applicant Information

Applicant:

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Application Correspondent:

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Contact Person:

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Date Prepared: **May 30th 2025**

II. Subject Device Identification

Device Trade Name:	VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set); VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set with shunt); VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood Cardioplegia Set Mini)
Classification Name:	Heat-Exchanger, Cardiopulmonary Bypass
Regulation Number:	21 CFR 870.4240
Product Code:	DTR
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Device

The *Vanguard Blood Cardioplegia Systems* are substantially equivalent to the following cleared predicate devices. Both modified and unmodified models have the same fundamental scientific technology and intended use:

Vanguard 4:1 Blood cardioplegia set (with and without shunt)	510(k) Number:	K934763
	Device Trade Name:	SORIN BLOOD CARDIOPLEGIA SYSTEM
	Classification Name:	Reservoir, Blood, Cardiopulmonary Bypass
	Regulation Number:	21 CFR 870.4400
	Product Code:	DTN
	Classification:	Class II
	Classification Panel:	Cardiovascular
Vanguard 4:1 Blood Cardioplegia Set Mini	510(k) Number:	K934847
	Device Trade Name:	NGBCD & NGBCDP CARDIOPLEGIA DELIVERY SYSTEMS
	Classification Name:	Reservoir, Blood, Cardiopulmonary Bypass
	Regulation Number:	21 CFR 870.4400
	Product Code:	DTN
	Classification:	Class II
	Classification Panel:	Cardiovascular

Note: These 2 predicates were classified as *Reservoir, Blood, Cardioplumonary Bypass* linked to the regulation number 21 CFR 870.4400 and to the product code DTN, but since the subject products are cardioplegia systems containing heath-exchangers, we believe that the correct classification should be *Heat-Exchanger, Cardiopulmonary Bypass* linked to the regulation number 21 CFR 870.4240 and to the product code DTR.

IV. Device Description

The Vanguard Blood Cardioplegia Systems are single-use, non-toxic, non-pyrogenic and supplied sterile in individual packs.
They are cardiopulmonary bypass devices allowing cardioplegia fluid delivery; they also regulate cardioplegia fluid temperature and trap air emboli.
Vanguard devices are indicated for use for patients undergoing surgical procedures requiring cardiopulmonary bypass procedures.
These Vanguard Blood Cardioplegia Systems are circuits designed to administer cardioplegic solution and they can be used up to 6 hours.

The *Vanguard Blood Cardioplegia Systems* are the modified version of the disposables currently marketed in the SORIN BLOOD CARDIOPLEGIA SYSTEM (K934763) and the NGBCD & NGBCDP CARDIOPLEGIA DELIVERY SYSTEMS (K934847).

V. Indications for Use

Vanguard 4:1 Blood cardioplegia sets are cardiopulmonary bypass devices allowing cardioplegia fluid delivery. They also regulate cardioplegia fluid temperature and trap air emboli. The devices are intended to be used for 6 hours or less.

VI. Summary of Technical Characteristics

The Vanguard Blood Cardioplegia Systems have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices.

The tubing and connectors of the Vanguard devices made of PVC materials were changed within the modified Vanguard Blood Cardioplegia Systems in order to remove the diethylhexyl phthalate (DEHP) used as plasticizer currently present in the device.

Moreover, the rigid connectors of the Vanguard devices made of PVC materials were changed within the modified Vanguard Blood Cardioplegia Systems in order to remove the DOTE used as thermal stabilizer.

Then, the PP Purell material of line clamps of the Vanguard devices was replaced within the modified Vanguard Blood Cardioplegia Systems with another PP material (Bormed); and the mesh Versapor material for the vented spike component of the Vanguard devices was replaced within the modified Vanguard Blood Cardioplegia Systems with another kind of Versapor material.

Additionally, some technical specifications for Vanguard Blood Cardioplegia Systems were updated and tested to better reflect the state of the art of the devices.

No other design changes have been made to the 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 Vanguard Blood Cardioplegia Systems, as disposables used to administer cardioplegic solution during surgical procedures requiring cardiopulmonary bypass procedures.

The Vanguard Blood Cardioplegia Systems 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 Vanguard Blood Cardioplegia Systems, as 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, as well as on equivalent performance testing, the Vanguard Blood Cardioplegia Systems can be deemed to be substantially equivalent to their predicate devices:

- the unmodified NGBCW4 Warm Blood Cardioplegia Delivery System 4:1 blood-to-crystalloid ratio and NGBCW4C Warm Blood Cardioplegia Delivery System 4:1 blood-to-crystalloid ratio with shunt for delivering 100% blood, cleared under K934763;
- the unmodified NGBCDP Reduced Priming Volume Blood Cardioplegia Delivery System 4:1 blood-to-crystalloid ratio, cleared under K934847;

The Vanguard Blood Cardioplegia Systems, 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.