April 25, 2025

Sorin Group Italia S.R.L.
Martina Carlini
Regulatory Affairs specialist
Via Statale 12 Nord, 86
Mirandola, MO 41047
Italy

Re: K243264
Trade/Device Name: DHF 0.2 Hemoconcentrator (DHF 02); DHF 0.6 Hemoconcentrator (DHF 06); SH 14 Hemoconcentrator (SH 14)
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI
Dated: November 13, 2024
Received: March 27, 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,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K243264

Device Name

DHF 0.2 Hemoconcentrator (DHF 02);
DHF 0.6 Hemoconcentrator (DHF 06);
SH 14 Hemoconcentrator (SH 14)

Indications for Use *(Describe)*

The hemoconcentrators are intended for use in cardiopulmonary bypass circuits for hemoconcentration and consequent restoring of patient physiological hematocrit. The choice of hemoconcentrator depends on the protocol being used and required filtration speed. The device is intended to be used for six 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.

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510(k) Summary

(in accordance with 21 CFR 807.92)

K243264

I. Applicant Information

Applicant:

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Contact Person:

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Application Correspondent:

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Contact Person:

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Date Prepared: **April 23rd, 2025**

II. Subject Device Identification

Device Trade Name:	DHF 0.2 Hemoconcentrator (DHF 02); DHF 0.6 Hemoconcentrator(DHF 06); SH 14 Hemoconcentrator (SH 14)
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	21 CFR 876.5860
Product Code:	KDI
Classification:	Class II

Classification Panel: Gastroenterology & Urology

Predicate Device

The *DHF and SH Hemoconcentrators* are substantially equivalent to the following cleared predicate devices. Both modified and unmodified models have the same fundamental scientific technology and intended use:

DHF 02 **DHF 06**	510(k) Number:	K021732
	Device Trade Name:	Dideco DHF hemoconcentrators
	Classification Name:	Dialyzer, high permeability with or without sealed dialysate system
	Regulation Number:	21 CFR 876.5860
	Product Code:	KDI
	Classification:	Class II
	Classification Panel:	Gastroenterology & urology
SH 14	510(k) Number:	K081313
	Device Trade Name:	SH 14 hemoconcentrators
	Classification Name:	Dialyzer, high permeability with or without sealed dialysate system
	Regulation Number:	21 CFR 876.5860
	Product Code:	KDI
	Classification:	Class II
	Classification Panel:	Gastroenterology & urology

III. Device Description

DHF and SH Hemoconcentrators are single-use, non-toxic and non-pyrogenic fluid path devices; they are supplied sterile and individually packaged. The devices are made of plastic materials and are recommended for use in cardiopulmonary bypass circuits for hemoconcentration and consequent restoring of patient's physiological hematocrit: The choice of hemoconcentrator depends on the protocol being used and required filtration rate. The device can be used up to 6 hours.

The *DHF and SH hemoconcentrators* are the modified version of the disposables currently marketed in the Dideco DHF hemoconcentrators (K021732) and the SH 14 hemoconcentrators (K081313).

IV.

Indications for Use

The hemoconcentrators are intended for use in cardiopulmonary bypass circuits for hemoconcentration and consequent restoring of patient physiological hematocrit. The choice of hemoconcentrator depends on the

protocol being used and required filtration speed. The device is intended to be used for six hours or less.

V. Summary of Technical Characteristics

The DHF and SH hemoconcentrators have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices.
The thermoplastic elastomer material of the two O rings placed between the device housing and the device blood header caps was changed with another elastomer material (from Santoprene to Silicone).
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.

VI. Non-Clinical Performance Data

Sorin Group Italia S.r.l. has conducted extensive verification and validation testing of the DHF and SH hemoconcentrators, as disposables used in cardiopulmonary bypass circuits for hemoconcentration and consequent restoring of patient's physiological hematocrit.
The DHF and SH hemoconcentrators comply with all the applicable voluntary standards related to Dialysers. The devices passed all the testing in accordance with national and international standards.

VII. Clinical Performance Data

No clinical testing was conducted in support of the DHF and SH hemoconcentrators, as the indications for use and technical characteristics are unchanged with respect 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.

VIII. Statement of Substantial Equivalence

Based on equivalent intended use and technological characteristics, as well as on equivalent performance testing, the DHF and SH hemoconcenttrators can be deemed to be substantially equivalent to their predicate devices:

- the unmodified DHF 02 / DHF 06, cleared under K021732;
- the unmodified SH 14, cleared under K081313;

The DHF SH hemoconcentrators, 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.