August 16, 2024

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

Re: K241236
Trade/Device Name: XTRA Collection sets; XTRA Sequestration set X
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: May 2, 2024
Received: July 18, 2024

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.

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

Digitally signed by Kathleen M. Grunder -S
Date: 2024.08.16 15:28:30 -04'00'

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)*

K241236

Device Name

XTRA Collection sets;
XTRA Sequestration set X

Indications for Use *(Describe)*

For XTRA Collection sets:
"The XTRA Autotransufion System (including the XTRA Collection sets) is indicated for intraoperative recovery of blood, washing of blood collected in the postoperative period, and preoperative sequestration (with indirect patient connection). Typical clinical applications of autotransfusion include the following surgical specialties:
• Cardiovascular
• Orthopedics
• Thoracic
• Transplant surgery
• Emergency (Trauma)
• Neurosurgery
• Obstetrics and Gynecology
• Urology"

For XTRA Sequestration set X:
"The XTRA Autotransufion System (including the XTRA Sequestration set X) is indicated for intraoperative recovery of blood, washing of blood collected in the postoperative period, and preoperative sequestration (with indirect patient connection). Typical clinical applications of autotransfusion include the following surgical specialties:
• Cardiovascular
• Orthopedics
• Thoracic
• Transplant surgery
• Emergency (Trauma)
• Neurosurgery
• Obstetrics and Gynecology
• Urology"

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: K241236

I. Applicant Information

Applicant:

SORIN GROUP ITALIA S.R.L.
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Contact Person:

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Application Correspondent:

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Contact Person:

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Date Prepared: **August 16th 2024**

II. Subject Device Identification

Device Trade Name:	XTRA Sequestration set X and XTRA Collection sets
Classification Name:	Apparatus, Autotransfusion
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Classification:	Class II
Classification Panel:	Anesthesiology

III. Predicate Device

The *XTRA Sequestration set X* is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	K101586
Device Trade Name:	XTRA autotransfusion system
Classification Name:	Apparatus, Autotransfusion
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Classification:	Class II
Classification Panel:	Anesthesiology

The *XTRA Collection set* is substantially equivalent to the following cleared predicate devices. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	K101586	K131103
Device Trade Name:	XTRA autotransfusion system	XRES/XRES 120µm Blood Collection Reservoirs
Classification Name:	Apparatus, Autotransfusion	Reservoir, blood, cardiopulmonary bypass
Regulation Number:	21 CFR 868.5830	21 CFR 870.4400
Product Code:	CAC	DTN
Classification:	Class II	Class II
Classification Panel:	Anesthesiology	Cardiovascular

IV. Device Description

XTRA Sequestration set X

The XTRA Sequestration set X is a single use sterile device made of plastic materials (mainly PVC) and it should be used in combination with a Bowl set and the XTRA autologous blood separation equipment unit (XTRA Equipment) for preoperative sequestration, aimed at autotransfusion.

The XTRA Sequestration set consists of a system of tubing lines and bags, the autologous blood is recovered from the patient through routine hemodilution techniques and it's mixing with an anticoagulant in a blood bag, when blood is sufficient to fill the bowl, the Bowl set blood processing starts in order to separate blood into red blood cells (RBC), platelet poor plasma (PPP) and

concentrated platelets or platelet rich plasma (PRP). In the bowl, because of centrifugal force the blood components are separated and the RBC, PPP and PRP are collected into collection bags while the undesired elements (lysed cells, residuals, water, etc.) are discarded into a waste bag. The blood processed and collected in the bags is then reinfused to the patient through gravity. The system does not provide any mechanical means of reinfusing the product.

The XTRA Sequestration set is a modified version of the disposable currently marketed in the XTRA autotransfusion system (K101586).

XTRA Collection sets
The XTRA Collection sets are single use sterile devices made of plastic materials (mainly PVC) and they should be used in combination with the XTRA autologous blood separation equipment unit (XTRA Equipment) for intraoperative cell salvage and/or postoperative cell salvage, aimed at autotransfusion.

The XTRA Collection sets consist of a blood collection reservoir, an aspiration and anticoagulation line, a vacuum extension line and a system of tubing lines, the autologous blood is collected from the field by mean of a vacuum source (vacuum pump provided into the equipment) into a blood collection reservoir and filtered to remove large clots, debris and microaggregate and blood defoaming. From the reservoir, the blood may be immediately used for direct administration to the patient in case of emergency, otherwise, the collected blood is processed with a Bowl set (wash set) and then reinfused to the patient through gravity. The system does not provide any mechanical means of reinfusing the product.

The XTRA Collection sets are a modified version of the disposables currently marketed in the XTRA autotransfusion system (K101586) and in the XRES/XRES 120µm Blood Collection Reservoirs (K131103).

V. Indications for Use

The XTRA Autotransufion System (including the XTRA Sequestration set X and the XTRA Collection sets) is indicated for intraoperative recovery of blood, washing of blood collected in the postoperative period, and preoperative sequestration (with indirect patient connection). Typical clinical applications of autotransfusion include the following surgical specialties:

- Cardiovascular
- Orthopedics
- Thoracic
- Transplant surgery
- Emergency (Trauma)
- Neurosurgery
- Obstetrics and Gynecology
- Urology.

VI. Summary of Technical Characteristics

The XTRA Sequestration set X and the XTRA Collection sets have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices.

Several components made of PVC materials were changed within the modified XTRA Sequestration set X and XTRA Collection sets in order to remove the diethylhexyl phthalate (DEHP) used as plasticizer currently present in the device.

Additionally, for the XTRA Collection sets, a new Aspiration and Anticoagulation line (AAL1/4-20ft) has been created. It will be identical to the AAL1/4, the only difference is in the length of the main tube of the line, which will be longer (20ft) then the current AAL1/4.

Moreover, the supplier of the 2-way drip chamber of the AAL lines (AAL1/4, AAL1/4-20ft and AAL1/4-3/8) has been changed so, also the component itself is changed. The current 2-way drip chamber and the new one are very similar, but the new one is slightly different in the design of the pipe bonding profile, which doesn't have a double wall anymore.

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 verification and validation testing of the XTRA Sequestration set and XTRA Collection sets, as disposable parts of an autotransfusion system capable of providing adequate blood collection from the operating field or from the extracorporeal circuit, washing and concentrating the blood products which then have to be reinfused to the patient.

The XTRA Sequestration set X and XTRA Collection sets comply with all the applicable voluntary standards related to Autotransfusion 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 XTRA Sequestration set X and XTRA Collection sets, 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 XTRA Sequestration set X and the XTRA Collection sets can be deemed to be substantially equivalent to their predicate devices, for the Sequestration set the disposable of the Unmodified XTRA Autotransfusion system, cleared under K101586, while, for the Collection sets the disposables of the Unmodified XTRA Autotransfusion system, cleared under K101586, and of the Unmodified XRES/XRES 120µm Blood Collection Reservoirs, cleared under K131103.

The XTRA Sequestration set X and XTRA Collection sets, 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, the disposables of the Unmodified XTRA Autotransfusion system and XRES/XRES 120µm Blood Collection Reservoirs.