April 29, 2024

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

Re: K240584
Trade/Device Name: XTRA Autotransfusion System (with XTRA Bowl Sets)
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: April 4, 2024
Received: April 4, 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.

510(k) Number *(if known)*
K240584

Device Name
XTRA Autotransfusion System (with XTRA Bowl Sets)

Indications for Use *(Describe)*

The XTRA Autotransfusion System (including the XTRA bowl set) 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.

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: 240584

I. Applicant Information

Applicant:

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

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Contact Person:

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Date Prepared: **April 26th 2024**

II. Subject Device Identification

Device Trade Name:	XTRA Autotransfusion System (with XTRA bowl 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 Autotransfusion System (with XTRA Bowl Sets) 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

IV. Device Description

The XTRA Autotransfusion System (with XTRA Bowl 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 preoperative sequestration, intraoperative cell salvage, and/or postoperative cell salvage, aimed at autotransfusion.

The XTRA Autotransfusion System (with XTRA Bowl Sets) consist of a disposable bowl pre-connected with a system of tubing lines and bags, the autologous blood is collected from the field by mean of a vacuum source (vacuum pump provided into the equipment), then the blood is pumped with a roller pump (provided into the equipment) into the bowl separation chamber and centrifuged. 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 Autotransfusion System (with XTRA Bowl Sets) are a modified version of the disposables currently marketed in the XTRA autotransfusion system (K101586).

V. Indications for Use

The XTRA Autotransfusion System (including the XTRA bowl set) 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 Autotransfusion System (with XTRA Bowl 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 Autotransfusion System (with XTRA Bowl Sets) in order to remove the diethylhexyl phthalate (DEHP) used as plasticizer and the Dioctyltinbis (2-ethyhexylthioglycolate (DOTE) used as stabilizer currently present in the device.
Additionally, a design change was introduced in the waste bag handle: the handle is now molded together with the waste bag and directly incorporated into this latter. No other design changes have been made to the device.
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 XTRA Autotransfusion System (with XTRA Bowl Sets), as a disposable part 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 Autotransfusion System (with XTRA Bowl Sets) complies with all the applicable voluntary standards related to Autotransfusion systems. 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 XTRA Autotransfusion System (with XTRA Bowl Sets), 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 XTRA Autotransfusion System (with XTRA Bowl Sets) can be deemed to be substantially equivalent to its predicate device, the disposable of the Unmodified XTRA Autotransfusion system, cleared under K101586.

The XTRA Autotransfusion System (with XTRA Bowl Sets), 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 disposable of the Unmodified XTRA Autotransfusion system.