November 16, 2023

Sorin Group Italia S.R.L.
Luigi Vecchi
Director, Regulatory Affairs
Via Statale 12 Nord, 86
Mirandola, IT 41037
Italy

Re: K231652
Trade/Device Name: D100 KIDS; D101 KIDS
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTN
Dated: October 6, 2023
Received: October 17, 2023

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,

Nicole M. Gillette -S

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.

Submission Number *(if known)*

Device Name

D100 KIDS;
D101 KIDS

Indications for Use *(Describe)*

The D100 devices are indicated for use for neonatal patients undergoing surgical procedures requiring cardiopulmonary bypass. The oxygenator is intended to be used for six hours or less.

The D101 devices are indicated for use for infant patients undergoing surgical procedures requiring cardiopulmonary bypass The oxygenator 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

Prepared on: 2023-06-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SORIN GROUP ITALIA S.R.L.
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Applicant Contact Telephone	+39 0535 29957
Applicant Contact	Mr. LUIGI VECCHI
Applicant Contact Email	luigi.vecchi@livanova.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	D100 KIDS; D101 KIDS
Common Name	Cardiopulmonary bypass oxygenator
Classification Name	Oxygenator, Cardiopulmonary Bypass
Regulation Number	870.4350
Product Code	DTZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K0601031	D100 KIDS	DTZ
K072091	D101 KIDS	DTZ

Device Description Summary

21 CFR 807.92(a)(4)

The D100 KIDS and D101 KIDS oxygenators (hereinafter identified as KIDS) consist of an oxygenator with an integrated heat exchanger and hard-shell cardiotomy venous reservoir.

The KIDS consist of the following main components
• a heat exchanger consisting of a grooved and pleated stainless steel that is placed into a polycarbonate housing with integrated Hansen connectors and is sealed with resin potting at both ends. it controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery.
• an oxygenating module element made of a coiled bundle of polypropylene microporous hollow fibers rolled on the heat exchanger sub assembly. The hollow fiber membrane provides oxygenation and carbon dioxide removal from venous blood or suction blood.
• a hard shell cardiotomy/venous reservoir attached to the top of the oxygenator by means of a molded fitting joint. It is a single chamber reservoir comprised of a rigid polycarbonate housing with an internal hollow support. The filtering system surrounds the internal hollow support and work as a cardiotomy section in the upper part and as a venous reservoir in the bottom part. It collects and filter blood coming from suckers and from the venous return.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The D100 devices are indicated for use for neonatal patients undergoing surgical procedures requiring cardiopulmonary bypass. The

oxygenator is intended to be used for six hours or less.

The D101 devices are indicated for use for infant patients undergoing surgical procedures requiring cardiopulmonary bypass The oxygenator is intended to be used for six hours or less

Indications for Use Comparison

21 CFR 807.92(a)(5)

same indications for use

Technological Comparison

21 CFR 807.92(a)(6)

same technological charcteristics

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject device was tested to ensure that it can provide all the capabilities necessary to operate safely and effectively. Applicable tests were carried out in accordance with the requirements of ISO 10993-1 standard as well as in compliance with the FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" of September 4, 2020.
In vitro testing was performed to evaluate the impact of the different materials in the modified KIDS version, specifically the following tests were carried on:
• pull test on modified adaptor kit and purge lines
• pressure resistance on modified adaptor kit
• backflow and pressure flow rate on modified one way valve
This performance testing was conducted on sterile aged devices; accelerated aging for a period of time equivalent to at least 3 years as per device labeling
The modified device successfully met all acceptance criteria.
The results of in vitro studies demonstrate that the subject Modified KIDS performs in a manner substantially equivalent to the Unmodified KIDS predicate device with respect to the relevant functional parameters
No clinical testing was conducted in support of this submission, as the indications for use are equivalent to those of their respective predicates, which have been on the market for many years. The non-clinical testing summarized in this submission supports the substantial equivalence of these devices with their respective predicates in relation to the changes subject of this submission