DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 08, 2017

Sorin Group Italia S.r.l
% Scott Light
Regulatory Affairs Manager
Sorin Group USA, Inc.
14401 W 65th Way
Arvada, Colorado 80004

Re: K161733
Trade/Device Name: INSPIRE SVR 1200
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: February 3, 2017
Received: February 6, 2017

Dear Mr. Light:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161733

Device Name
INSPIRE SVR 1200 (Softshell Venous Reservoir)

Indications for Use *(Describe)*

INSPIRE SVR 1200 with Ph.I.S.I.O. coating is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects and handles venous blood and suction blood from cardiotomy reservoir. The INSPIRE SVR 1200 is 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

SUBMITTER: Sorin Group Italia
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41037 Mirandola (MO) Italy

CONTACT PERSON: Luigi Vecchi
Phone: 39 0535 29811
Fax: 39 0535 25229

DATE PREPARED: March 8, 2017

TRADE NAMES: INSPIRE SVR 1200 soft shell venous reservoir.

COMMON NAMES: Soft shell venous reservoir.

CLASSIFICATION NAMES: Cardiopulmonary Bypass Blood Reservoir
(21 CFR 870.4400, Product Code DTN)

PREDICATE DEVICE: BMR 1900 Ph.I.S.I.O.Venous Reservoir Bag (K112771)

REFERENCE DEVICE: CBMVR800 Venous Reservoir Bag (K920774)

DEVICE DESCRIPTION:

The Sorin INSPIRE SVR 1200 (hereinafter referred to as INSPIRE SVR 1200) is a flexible PVC soft shell venous reservoir bag. This reservoir may be attached to the INSPIRE 6F C and INSPIRE 8F C oxygenator systems using a molded fitting connected to the gas exchange module. The blood contacting surfaces of this device are coated with a phosphorylcholine-based (Ph.I.S.I.O.) coating that provides a uniform surface. The device is provided with a 1/2" venous inlet connector and a 3/8" blood outlet connector. The venous inlet has an integral cardiotomy reservoir connector to allow receipt of blood from both venous cannulation and from a cardiotomy reservoir.

The INSPIRE SVR 1200 can be operated at flow rates up to 8 liters per minute (l/min) and has a maximum reservoir volume of 1325 mL.

INDICATION FOR USE:

INSPIRE SVR 1200 with Ph.I.S.I.O. coating is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects and handles venous blood and suction blood from cardiotomy reservoir. The INSPIRE SVR 1200 is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The modified device has the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate devices.

The INSPIRE SVR 1200 soft shell venous reservoir is similar to the predicate devices as it consists of a soft PVC material and is used to collect blood during cardiopulmonary bypass procedures lasting up to 6 hours. The intended use and principles of operation are consistent with the predicate devices. It differs from the predicate devices in volume and dimensions, length of purge lines, and it includes a mounting backplate.

The device is ethylene oxide sterilized, has a non-pyrogenic fluid path and is for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were conducted in accordance with the requirements of ISO 10993-1. The current draft Guidance “Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” and its guidelines was also considered limited to external communicating device, circulating blood, limited contact duration.

In vitro testing was conducted on the INSPIRE SVR 1200, the subject of the present 510(k).

The tests performed on INSPIRE SVR 1200 demonstrate it is substantially equivalent to the predicate devices.

Testing was conducted in accordance with the relevant requirements of “Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA, November 29, 2000”.

The following list provides the performance tests conducted to demonstrate compliance of INSPIRE SVR 1200 to the product’s performance specifications and predicate devices substantial equivalency.

The INSPIRE SVR 1200 successfully met all acceptance criteria for each of the following tests:

- Biocompatibility (cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, hemocompatibility, and genotoxicity)
- Blood trauma
- Leaching of coating
- Surface modification integrity
- Surface modification coverage
- Filtration efficiency
- Air challenge performance

- Flow rate capacity
- 2h continuous use at 0.5 LPM
- Maximum operating volume
- Minimum operative volume at different flow rates
- Pressure drop
- Structural integrity
- Blood pathway integrity
- Burst testing
- Sterility
- Package integrity

CONCLUSIONS:

The results of in vitro studies demonstrated that the INSPIRE SVR 1200 performs in a manner substantially equivalent to the BMR 1900 Ph.I.S.I.O. and CBMVR800 predicate devices with respect to the relevant functional parameters.

Test results of this study demonstrate the predicate devices substantial equivalence with respect to device function.