K092315

510(k) SUMMARY

AUG 12 2009

SUBMITTER:

Sorin Group Italia S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

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DATE PREPARED:

July 29, 2009

DEVICE TRADE NAME:

Sorin VVR 4000i and Sorin VVR 4000i SMARxT (hereafter referred to as Modified VVR 4000i)

COMMON NAME:

Sealed Filtered Hardshell Venous Reservoir with Integral Cardiotomy Filter

CLASSIFICATION NAME:

Cardiopulmonary Bypass Blood Reservoir with Defoamer

Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter

UNMODIFIED DEVICE

COBE VVR 4000 and COBE SMAR$_X$T VVR 4000 Filtered Hardshell Venous Reservoirs (hereafter referred to as Unmodified VVR 4000i) (#K004046)

DEVICE DESCRIPTION:

SORIN VVR 4000i and SORIN VVR 4000i SMARxT Filtered Hardshell Venous Reservoirs are sealed hardshell venous blood reservoirs with a defoamer and integral cardiotomy filter.
The devices are supplied ethylene oxide sterilized with non-pyrogenic fluid pathways and are for single use only. They defoam, filter and store the blood coming from the operating field through thoracic, intracardiac and general suction.
The devices are a modified version of the currently marketed COBE VVR 4000 and COBE SMAR$_X$T VVR 4000 Filtered Hardshell Venous Reservoirs

(#K004046). The differences in design consist of the addition of a 41 micron pore size polyester net in the filtering section for enhanced defoaming capability and the addition of two ports (one female luer lock port and one cardiotomy luer lock port) on the reservoir lid for user convenience. Notwithstanding the modification, no new materials have been used since the added polyester net consists of the same polyester sock which constitutes the filter housing. Another modification concerns the transfer of the manufacturing site from Sorin Group USA, Inc. to Sorin Group Italia S.r.l. As a consequence of these three minor modifications, the labeling has to be updated.

The design modification enables the device to better defoam the blood suctioned from the operative field during cardiopulmonary bypass procedures. The Modified VVR4000i and Unmodified VVR4000i are similar in their intended use, materials and manufacturing processes.

INDICATION FOR USE:

Sorin VVR 4000i and Sorin VVR 4000i SMARxT are intended to be used in surgical procedures requiring cardiopulmonary bypass for periods up to six hours.

TECHNOLOGICAL CHARACTERISTICS:

The Modified VVR 4000i is identical to the Unmodified VVR 4000i with respect to intended use, materials, biocompatibility and performance of the SMA treatment, operating principles, control mechanisms, fundamental scientific technology and manufacturing process. The differences in design consist of the addition of a polyester net in the filtering section for enhanced defoaming capability and the addition of a female luer lock port and a cardiotomy luer lock port on the reservoir lid for user convenience.

The SMA treatment of the Modified VVR 4000i is identical to that used on Unmodified VVR 4000i. The materials and manufacturing process in regards to the SMA treatment are unchanged with respect to the unmodified device

NON CLINICAL TEST RESULTS:

A complete battery of Biocompatibility tests to be performed in accordance with the requirements of ISO 10993-1 and the FDA May 1, 1995 Memorandum has not been carried out since there are no new materials in blood contact with respect to the unmodified VVR4000i.

The polyester used in the net is, in fact, already used into the device. Accordingly, the complete battery of Biocompatibility testing has not been carried out on the

basis of a concrete rationale and a cross reference has been referred to the 510(k) submission of the unmodified device (#K004046).
Similarly, the package integrity testing has not been performed since the packaging is unchanged from unmodified device. For this reason this 510(k) cross references packaging data previously submitted for the unmodified device (#K004046).

IN VITRO TEST RESULTS:

In vitro testing was performed in order to provide the data necessary to demonstrate both the substantial equivalence with the unmodified device and also to comply with safety and effectiveness requirements.
The tests were carried out in accordance with the requirements of the "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000. The aged device was tested for *in vitro* pressure drop, haemolysis/cell depletion, wetting volume (breakthrough times/volumes & priming volume (static)), filter flow rate capacity and defoaming efficiency, and dynamic priming volume (hold-up volumes).
The results of these tests met established specifications. This 510(k) cross-references performance data previously acquired for the Unmodified VVR 4000i since, as above stated, these aspects are not affected by the modification.

CONCLUSIONS:

The Modified VVR 4000i device performs in a manner substantially equivalent to the Unmodified VVR 4000i with respect to biocompatibility and the functional parameters in common with the unmodified device. Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Italia S.r.l.
c/o Mr. Barry Sall
Principal Consultant
200 West Street
Waltham, MA 02451

AUG 12 2009

Re: K092315
VVR 4000i and VVR 4000i SMAR$_x$T Filtered Hardshell Venous Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood defoamer
Regulatory Class: Class II (two)
Product Code: DTN, DTP, JOD
Dated: July 29, 2009
Received: July 30, 2009

Dear Mr. Sall:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K092315

Device Name: Sorin VVR 4000i and Sorin VVR 4000i SMARxT Filtered Hardshell Venous Reservoirs.

Indication for Use:

Sorin VVR 4000i and Sorin VVR 4000i SMARxT filtered hardshell reservoirs are intended to be used in surgical procedures requiring cardiopulmonary bypass for periods up to six hours.

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahmen

(Division Sign-Off)
Division of Cardiovascular Devices

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