510(k) SUMMARY

K093601

SUBMITTER: Sorin Group Italia
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DEC 18 2009

DATE PREPARED: November 16, 2009

DEVICE TRADE NAME: Sorin AF 840 Ph.I.S.I.O.

COMMON NAME: Arterial Filter

CLASSIFICATION NAME: Cardiopulmonary Bypass Arterial Line Blood Filter

UNMODIFIED DEVICES: D734 MICRO 40 Ph.I.S.I.O. Adult Arterial Filter

DEVICE DESCRIPTION:

The AF 840 Ph.I.S.I.O. is sterile, non-pyrogenic disposable filter for use in the arterial line of the cardiopulmonary bypass circuit with flow rate not exceeding 8.0 liters/minute. The AF 840 Ph.I.S.I.O. is an Arterial Filter with 40 micron filters screen designed to remove potentially harmful gaseous emboli, aggregated blood constituents, and particulate debris, greater than the pore size, from the arterial line perfusate. The AF 840 Ph.I.S.I.O. is a modified version of the currently marketed D734 MICRO 40 Ph.I.S.I.O.
The main changes include: a different orientation of the blood outlet port for improved ease of use, ergonomics and fluid dynamic properties, change from polyurethane potting to ultrasonic welding for improved overall biocompatibility, the size of the filter housing has been reduced thus the filter net is double pleated rather than single pleated and different formulation of phosphorylcholine monomer to improve wettability. As a consequence of these modifications, the labeling has been updated.

The modified device has unchanged intended use, operating principles, control mechanisms, manufacturing process, sterilization process and fundamental scientific technology.

The manufacturing process in regards to the coating is also unchanged with respect to the unmodified device.

INDICATION FOR USE:

The AF 840 Ph.I.S.I.O. Arterial Filter with 40 micron screen with phosphorylcholine coating is recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass, for periods up to six hours of use. The filter is effective in trapping and removing gaseous emboli as well as particulate debris that may be introduced through the arterial line.

TECHNOLOGICAL CHARACTERISTICS:

The AF 840 Ph.I.S.I.O. Arterial Filter has the same control mechanisms and operating principles when compared to the unmodified device. The size of the filter housing has been reduced and the polyester net of the filter screen is now double pleated rather than the single pleated filter configuration of the unmodified device.

The AF 840 Ph.I.S.I.O. Arterial Filter utilizes the same filtering medium. The proposed AF 840 Ph.I.S.I.O. presents a different formulation of the same phosphorylcholine monomer. Such different formulation has already been used in other products already cleared in US. No new materials are used as a result of these changes.

The current port orientation is parallel to the main axis so that the blood outlet flow is now parallel to the housing centerline.

No change to the intended use has been made as a result of these modifications. There are no differences in packaging type and material between AF 840 Ph.I.S.I.O. Arterial Filter and the D734 modified device.

The AF 840 Ph.I.S.I.O. Arterial Filters are ethylene oxide sterilized and have a non-pyrogenic fluid path. They are for single use only.

NON CLINICAL TEST RESULTS:

A complete battery of tests was carried out in accordance with the requirements of ISO 10993 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials.
Testing was performed on devices accelerated aged to an equivalent of three years real time aging. Sterility, Pyrogenicity, ETO residuals, Hemolysis, Acute Systemic Toxicity, Mutagenicity, Cytotoxicity, Irritation, Sensitisation, Haemocompatibility, were conducted as also the package integrity test.

The results of the testing met established specifications.

IN VITRO TEST RESULTS:

In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" Final Guidance for Industry, dated November 29, 2000 necessary to demonstrate both the substantial equivalence with the unmodified device and also to comply with safety and effectiveness requirements. The device was aged up to 3 years (+ 1 additional year of aging in order to test a truly worst case) and tested for operating blood volume, structural integrity test, pressure integrity test, pressure drop, filter flow rate capacity, in vitro haemolysis/cell depletion, filtration efficiency, leaching of the coating and air handling characteristics. For comparative purposes all tests, when applicable, were performed on sterilized aged devices comparing the AF 840 Ph.I.S.I.O Arterial Filters vs. the unmodified devices operated at same max blood flow. The results of these tests met established specifications

CONCLUSIONS:

The AF 840 Ph.I.S.I.O. arterial filter performs in a manner substantially equivalent to the D734 unmodified device 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.
In conclusion test result of this study suggests the AF 840 Ph.I.S.I.O. arterial filter is equivalent to the D734 MICRO Ph.I.S.I.O. arterial filters with respect to device function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

DEC 18 2009

Re: K093601
AF 840 Ph.I.S.I.O Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Filter, Blood, Cardiopulmonary Bypass, Arterial Line
Regulatory Class: Class II (two)
Product Code: DTM
Dated: November 19, 2009
Received: November 20, 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 (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.

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,

Donna R. Vachner

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): K093601

Device Name: Sorin AF 840 Ph.I.S.I.O.
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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093601