K083451

MAR 4 2009

SECTION 5, 510(k) Summary

Company Information:

Smiths Medical ASD, Inc.
10 Bowman Dr.
Keene, NH 03431
(603) 352-3812, prompt 4, ext 2923
Contact: Cynthia Engelhardt
Regulatory Affairs Specialist

Summary Prepared: March 3, 2009

Product Name:

Trade Name: Portex® Epidural Filter

Common Name: Epidural Filter

Classification Name: Filter, Conduction, Anesthetic (Class II, Product Code BSN)

Predicate Device(s):

Unknown, B. Braun Medial Inc. 0.22 Micron Flat Epidural Filter

Device Description:

The Portex® Epidural Filter is a 0.2µm (micron) filter used in epidural anesthesia for the filtration of aqueous drugs and is designed to help protect the patient from injected microorganisms or particulate matter. The Filter is comprised of a 0.2µm supported membrane enclosed in a modified acrylic leak proof transparent housing with male Luer with a rotating Locking Hub and a female Luer Lock.

The filtration area is 5.25 cm^2, has a flow rate of ≥ 200ml/Min @ 45 psi and can withstand a pressure of ≥ 115 psi during bolus injections.

The priming volume of the filter is 0.8 ml and the hold up volume is 0.45 ml as determined by weight. The filter has a bubble point of ≥46psi. The filter has 100% bacterial retention.

Indications for Use:

An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

Technological Characteristics:

The design of the proposed filter is similar to the predicate device. Both are a round flat filter with male and female Luer lock fittings. Both of the devices are a hydrophilic membrane enclosed in a plastic housing. The proposed is comprised of a 0.2micron filter and the predicate of a 0.22 micron filter.

All statements and representations set forth herein regarding or related to "substantially equivalent" or "substantial equivalence" are in the limited context of the definition and purpose of substantial equivalence in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations of the Food and Drug Administration, and are not made in the context of, for any purpose related to, or as an admission against interest under, any other laws or regulations, including patent laws (whether in the context of patent infringement or otherwise).

Non-Clinical Data:

Data submitted demonstrates that the epidural filter performs equivalently to the predicate device. Data submitted covers; dimensional characteristics, flow rate, bubble point, ISO 594-1 and ISO 594-2 testing and bacterial retention.

Clinical Data:

Not required.

Conclusion:

The proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Cynthia Engelhardt 03/03/09

Cynthia Engelhardt
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2009

Ms. Cynthia Engelhardt
Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

Re: K083451
Trade/Device Name: Epidural Filter
Regulation Number: 21 CFR 868.5130
Regulation Name: Anesthesia Conduction Filter
Regulatory Class: II
Product Code: BSN
Dated: February 26, 2009
Received: February 27, 2009

Dear Ms. Engelhardt:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K083451

Device Name: **Epidural Filter**

Indications for Use:

An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083451