K062005

smiths

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OCT 1 8 2006

510(K) SUMMARY:

Company Information:

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

Summary Prepared: July 14, 2006

Product Name:

Trade Name: **Portex® Epidural Catheter**

Common Name: Anesthesia Conduction Catheter

Classification Name: Anesthesia Conduction Catheter (21 CFR 868.5120, Product Code BSO)

Predicate Device(s):

K992471, SIMS Portex Epidural Catheter

Device Description:

The epidural catheter is made of flexible, nylon tubing. The catheters have a yellow radiopaque stripe. The catheter may be closed-ended with eyes or open-ended with a finished tip. The catheter has a marked tip with a single mark at 5cm from tip with 1cm increments, up to 15cm. The 10cm mark is indicated by two marks, 15cm by three marks, and 20cm by four marks.

The catheter is available in 20g (O.D. 1.05 mm/ I.D. 0.52 mm) or 21G (O.D. 0.83 mm/ I.D. 0.41 mm) sizes. The catheters have a nominal length of 36 inches.

Indications for Use:

The Epidural Catheter is indicted for the injection of local anesthetics into the epidural space. The duration of use should not exceed 72 hours.

Substantial Equivalence:

The substantial equivalence of the Epidural Catheter is supported by its similarities in design features, performance and indications for use to the SIMS Portex® Epidural Catheter (K992471).

Summary of Testing:

All materials used in the fabrication of the Epidural Catheter were evaluated through biological qualification safety tests as outlined in ISO 10993-1 Part 1 "Biological Evaluation of Medical Devices". Design control activities have been completed and the results indicate that the subject device is safe and effective.

Cynthia Engelhardt
Associate Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2006

Ms. Cynthia Engelhardt
Associate Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431-0724

Re: K062005
Trade/Device Name: Portex® Epidural Catheter
Regulation Number: 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: September 26, 2006
Received: September 27, 2006

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K062005

Device Name: Portex® Epidural Catheter

Indications for Use:

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Prescription Use √ (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: K062005