K090216

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MAY - 1 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: January 30, 2009

Product Name:

Trade Name: Epidural Anesthesia Needles

Common Name: Epidural Anesthesia Needles

Classification Name: Needle, Conduction, Anesthetic (W/Wo Introducer) (21 CFR 868.5150, Product Code BSP)

Predicate Device(s):

K000495, Ballard Medical Products Epidural and Spinal Needles (Now Kimberly Clark)

Device Description:

Epidural needles are instruments used for the injection of anesthetic agents into the epidural space or to facilitate the placement of an epidural catheter into the epidural space for continuous infusion of anesthetic agents into the epidural space for subsequent pain relief if required.

The needle consists of a plastic Luer hub, a stainless steel cannula, a plastic stylet and removable wings. The needle cannula has 10cm depth markings on it to assist in the needle placement.

The needles are provided as sterile, single use, disposable devices. They may be packaged individually or included in our regional anesthesia trays. The needles are provided with a Tuohy point in both 17g and 18g sizes.

Indications for Use:

An Epidural Needle is indicated for the injection of anesthetic agents into the epidural space or to facilitate the placement of an epidural catheter.

Technological Characteristics:

The Smiths Medical Epidural Anesthesia Needles have the same technological characteristics as the predicate devices identified above. The Smiths Medical Epidural Anesthesia Needles are equivalent in design, physical dimensions, Luer hub, metal and plastic materials to the predicate devices.

The Smiths Medical Epidural Anesthesia Needles general design characteristics and functionality are similar in that they meet performance standards where applicable for:

Stainless Steel components: ISO 9626
Hub: ISO 594-1 and ISO 594-2
Hub to Needle Bond Strength: ISO 7864

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 needle performs equivalently to the predicate device. Data submitted covers visual, performance and dimensional characteristics

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
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

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

Re: K090261
Trade/Device Name: Epidural Anesthesia Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: January 30, 2009
Received: February 3, 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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
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): K090261

Device Name: **Epidural Anesthesia Needles**

Indications for Use:

An Epidural Needle is indicated for the injection of anesthetic agents into the epidural space or to facilitate the placement of an epidural catheter.

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)

L Schuettler

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090261