K092657

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Smiths Medical ASD Inc.
Smiths Medical North America
10 Bowman Drive
Keene, NH 03431 0724, USA
T: +1 603 352 3812
F: +1 603 355 8157
www.smiths-medical.com

510(k) Summary
(Per 21 CFR 807.92)

NOV - 4 2009

1. Sponsor

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431
Tel: +1 603-352-3812, prompt 4, x2923
Fax: +1 603-352-6412
Primary Contact: Cindy Engelhardt

Date Prepared: August 26 2009

2. Device Name

Proprietary Name:	SIMS Regional Anesthesia Trays
Common/Usual Name:	Anesthesia conduction kits
Classification Name:	Anesthesia conduction kits

3. Predicate Devices

SIMS Regional Anesthesia Trays (K965017)

4. Device Description

The EpiFuse™ Catheter Connector is an alternate catheter connector for inclusion in the SIMS Regional Anesthesia Tray.

The EpiFuse™ Catheter Connector consists of two halves joined by a living hinge. The main body contains an elastomeric tube. The catheter is inserted into the input hole at the base of the connector and is retained by the elastomeric tube when the two halves of the connector are folded together. The elastomeric tube also creates a seal to prevent leakage. The design of the modified EpiFuse™ Catheter Connector allows the user to close the device with one hand while holding the catheter with the other. To release the catheter, a Luer slip device is inserted into the release aperture and the two halves of the connector will separate allowing removal of the catheter.

The key features and benefits of the EpiFuse™ Catheter connector include a yellow connector body for easy identification as Epidural during clinical use. The EpiFuse™ Catheter Connector is designed for use with 19G, 20G, and 21G epidural catheters. It

offers one hand activation for a simplified ease of use and includes a secure locking mechanism to reduce the risk catheter disconnection.

5. INTENDED USE/INDICATIONS FOR USE

The SIMS Regional Anesthesia Tray is intended to be used to administer patient regional or local anesthesia.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The SIMS Regional Anesthesia Tray is comprised of various procedural components including needles, syringes, fenestrated drape, Touhy epidural needles and EpiFuse™ Catheter connector.

7. PERFORMANCE TESTING

Verification/validation testing confirm that the EpiFuse™ Catheter Connector is suitable for use with 19G, 20G, and 21G epidural catheters and is safe and effective for its intended use as a component of the SIMS Regional Anesthesia Tray.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Cynthia Engelhardt
Regulatory Affairs Specialist

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

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

NOV - 4 2009

Re: K092657
Trade/Device Name: SIMS Regional Anesthesia Tray
Regulation Number: 21CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: October 16, 2009
Received: October 19, 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 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,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Division 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):

Device Name: SIMS Regional Anesthesia Tray

Indications for Use:

The SIMS Regional Anesthesia Tray is used to administer patient regional or local anesthesia.

Prescription Use X AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

510(k) Number: K92657