K051524

JUL - 7 2005

smiths

Smiths Medical ASD, Inc.
Anesthesia and Safety Devices Division
10 Bowman Drive
Keene NH 03431-0724 USA
Tel: +1 603 352 3812
Fax: +1 603 352 3703
www.smiths-medical.com

J: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

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

PREPARATION DATE OF SUMMARY:

June 7, 2005

TRADE NAME:

Lock-It™ Plus Regional Anesthesia Catheter Securement Device

COMMON NAME:

Accessory to Regional Anesthesia Conduction Catheter

PRODUCT CLASS/CLASSIFICATION:

Class II, 73 BSO, 21 CFR 868.5120

PREDICATE DEVICE(S):

StatLock II Epidural Securement Device, K943038.

DESCRIPTION:

The Lock-It™ Plus regional anesthesia catheter securement device consists of an adhesive backed polyethylene foam pad, with a clear molded plastic latch mechanism securely adhered to the top surface of the foam pad.

The regional anesthesia catheter securement device is available for use with catheters using 16/17gauge needles.

The regional anesthesia catheter securement device is provided individually packaged or in anesthesia conduction kits.

INDICATIONS FOR USE:

The regional anesthesia catheter securement device is a sterile single use securement device intended for securing regional anesthesia catheters at the skin insertion site to help prevent catheter migration. The maximum period of use is 7 days.

TECHNICAL CHARACTERISTICS:

The design of the proposed catheter securement device is similar to the predicate device. Both devices are designed to minimize catheter migration. Both devices are made of molded polycarbonate bonded to a foam pad. The technical characteristics of the two devices show no significant differences.

NON-CLINICAL DATA:

Data submitted demonstrates that the catheter securement device performs equivalently to the predicate device. Data submitted covers; percent flow restriction, catheter retention force and tape adhesion force.

CLINICAL DATA:

A clinical user evaluation has been conducted at three sites OUS (outside the U.S.): Royal Free Hospital, Ipswich Hospital and Lewisham Hospital. The intention of this user evaluation was not to compare the device to the predicate indicated in this 510(k) submission, rather to inquire as to the performance characteristics as compared to a device marketed by our sister company Smiths Medical International (UK) and sold exclusively to the OUS market. The clinical user evaluation concluded that the proposed device was equal to or better than a device currently sold by Smiths Medical International (UK).

This user evaluation provided useful support that the device performs as intended.

CONCLUSION:

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

Very truly yours,

SMITHS MEDICAL ASD, INC.

Cynthia Engelhardt
Associate Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2005

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

Re: K051524
Trade/Device Name: Lock-It™ PLUS Regional Anesthesia Catheter Securement Device
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: June 7, 2005
Received: June 8, 2005

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.

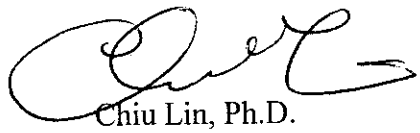
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

B: INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Lock-It™ PLUS Regional Anesthesia Catheter Securement Device

Indications for Use:

The regional anesthesia catheter securement device is a sterile single use securement device intended for securing regional anesthesia catheters at the skin insertion site to help prevent catheter migration. The maximum period of use is 7 days.

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 K051524