K090884

5. 510(k) SUMMARY

JUN 29 2009

APPLICANT/ SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Angela J. Caravella
Sr. Regulatory Affairs Analyst
Phone: 610-596-2966
Fax: 610-596-2502
E-mail: Angela.Caravella@bbraun.com

DEVICE NAME: Perifix ONE® Pediatric Catheter, 20 Ga. & 24 Ga.

COMMON OR USUAL NAME: Pediatric Nerve Block/ Epidural Catheter

DEVICE CLASSIFICATION: Class II, Product Code BSO, 21 CFR 868.5120

PREDICATE DEVICES: B. Braun Medical Regional Anesthesia Catheter (K042488), Smiths Medical ASD, Inc. Portex ® 24 Ga. Pediatric Epidural and Peripheral Block Anesthesia Catheter (K033080) PAJUNK Pediatric epidural catheter (K062902)

DESCRIPTION: B. Braun's Perifix ONE® Pediatric Catheter is a co-extruded anesthesia conduction catheter consisting of an inner layer of polyamide and an outer layer of polyurethane. The catheters will be available in 20 Ga. and 24 Ga. diameters. The 20 Ga. catheter will have a length of 1010 millimeters and the 24 Ga. catheter will have a length of 720 millimeters. The catheters are designed in a rounded closed tip configuration with six side ports for distribution of anesthetics and analgesics. Both catheters will have depth markings beginning within 2 millimeters from the tip of the catheter and ending at approximately 180 millimeters from the tip. The product is an individually packaged, sterile, non-pyrogenic, single use disposable device.

INTENDED USE:

The B. Braun Perifix ONE® Pediatric Catheter is intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery for pediatric patients within the subgroups of Child (2 to 12 years of age) and Adolescent (12 to 21 years of age). Routes of Administration include epidural and perineural (peripheral nerve block) with a duration of use no longer than 72 hours.

SUBSTANTIAL EQUIVALENCE:

The Perifix ONE® Pediatric Catheter is similar in design, function, and intended use to the predicate device, the currently marketed B. Braun Medical Inc. Regional Anesthesia Catheter. The Perifix ONE® Pediatric Catheter and the B. Braun Regional Anesthesia Catheter have a similar intended use since they both provide infusion of local anesthetics and analgesics to the epidural space or near a nerve.

The Perifix ONE® Pediatric Catheter and the B. Braun Regional Anesthesia Catheter both are sterile, individually packaged, single use, disposable catheters. They are both composed of the same materials and components, have the same basic design and are manufactured using similar processes. The only difference between the Perifix ONE® Pediatric Catheter and the B. Braun Regional Anesthesia Catheter is designed for pediatric use among Children (2 to 12 years of age) and Adolescents (12 to 21 years of age). As a result of the pediatric use, the Perifix ONE Pediatric Catheters will also possess different catheter depth markings with the small gauge size of 20 and 24 Ga.

The Perifix ONE® Pediatric Catheter is also similar to the Smiths Medical ASD, Inc. Portex® 24 Ga. Pediatric Epidural and Peripheral Block Anesthesia Catheter. Both the proposed and this 24 Ga. predicate device are labeled for pediatric use and are intended for children (2 to 12 years of age). Both are used for providing infusion of local anesthetics and analgesics to the epidural space or peripherally.

SUBSTANTIAL EQUIVALENCE:
(continued)

The Perifix ONE® Pediatric Catheter is also similar to the PAJUNK Pediatric Epidural Catheter. Both devices are intended for use within the pediatric population. The Perifix ONE® Pediatric Catheter and the PAJUNK Pediatric Epidural Catheter are both available in the 20 Ga. diameters for the infusion of local anesthetics and analgesics to the epidural space.

The Perifix ONE® Pediatric Catheter has been subjected to a variety of tests to demonstrate substantial equivalence to the three predicate devices and to demonstrate the safety and effectiveness of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Ms. Angela J. Caravella
Senior Regulatory Affairs Analyst
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K090884
Trade/Device Name: Perifix ONE® Pediatric Catheter, 20 Ga. & 24 Ga.
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: March 27, 2009
Received: March 31, 2009

Dear Ms. Caravella:

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.

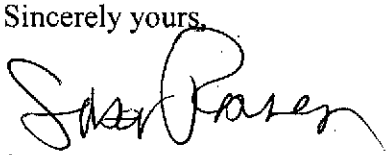
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Perifix ONE® Pediatric Catheter, 20 Ga. & 24 Ga.

Indications For Use:

The B. Braun Perifix ONE® Pediatric Catheter is intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery for pediatric patients within the subgroups of Child (2 to 12 years of age) and Adolescent (12 to 21 years of age). Routes of Administration include epidural and perineural (peripheral nerve block) with a duration of use no longer than 72 hours.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

)ivision Sign-Off)
·ivision of Anesthesiology, General Hospital
ection Control, Dental Devices

0(k) Number: K090884