SEP 30 2004 K042488

1.3 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2597

Contact: Amy Smith, RAC

DEVICE NAME:

B. Braun Regional Anesthesia Catheter
Epidural Tradename – Perifix® Catheter
Peripheral Nerve Block Tradename – Contiplex® Catheter

COMMON OR USUAL NAME:

Epidural / Nerve Block Catheter

DEVICE CLASSIFICATION:

Anesthesia Conduction Catheter
21 CFR Part 868.5120, Product Code BSO

PREDICATE DEVICE:

Csen Ltd, Combined End-Multiple Lateral Hole Epidural Catheter, K951927
B. Braun Medical Inc., B. Braun Nerve Block Catheter, K030380

DESCRIPTION:

The B. Braun Regional Anesthesia Catheter is a co-extruded anesthesia conduction catheter consisting of an inner layer of polyamide and an outer layer of polyurethane. The catheter will range in length from 400 – 1010 millimeters and will be available in both 19 and 20 Ga. diameters. The catheter will be available in an open tip configuration as well as a closed tip configuration. The closed tip catheters will have a rounded closed tip with six side ports for distribution of anesthetics and analgesics. The catheter will also have depth markings beginning within 50.5 millimeters from the tip of the catheter and ending at approximately 250 millimeters from the tip.

INTENDED USE:

The B. Braun Regional Anesthesia Catheter is a device 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 pre-operative, perioperative and postoperative periods

associated with general and orthopedic surgery as well as labor and delivery. Routes of administration include epidural and perineural (peripheral nerve block).

SUBSTANTIAL EQUIVALENCE:

The new B. Braun Regional Anesthesia catheter is similar in size, application, performance and sterilization methods to the B. Braun Nerve Block Catheter (K030830). Both of these catheters are available in open and closed tip configurations and are provided in the same lengths. The new B. Braun Regional Anesthesia catheter is similar in application and characteristics to the Csen Ltd Combined End-Multiple Lateral Holes Epidural catheter (K951927). Both of these catheters contain multiple side ports to allow for distribution of anesthetics and analgesics. The indications for use for the subject device combines both the epidural and peripheral nerve block applications of the predicate devices.

The new B. Braun Regional Anesthesia catheter is different from the predicate devices in that it is a coextruded catheter with both polyamine and polyurethane. Additionally, to aid in locating the device radiographically, three barium sulfate radiopaque stripes are included instead of only one tungsten stripe. The subject device also has six side port holes while the predicate devices have either seven or three. The effect of these material and side port differences was evaluated by performance and functionality testing. The result of this testing does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2004

Ms. Amy Smith
Senior Regulatory Affairs Specialist
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K042488
Trade/Device Name: B. Braun Regional Anesthesia Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: September 10, 2004
Received: September 13, 2004

Dear Ms. Smith:

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/dsma/dsmamain.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

1.2 Indications for Use Statement

510(k) Number (if known): K042488

Device Name: B. Braun Regional Anesthesia Catheter

Indications For Use:

The B. Braun Regional Anesthesia Catheter is a device 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 pre-operative, perioperative and postoperative periods associated with general and orthopedic surgery as well as labor and delivery. Routes of administration include epidural and perineural (peripheral nerve block).

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)

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

510(k) Number K042488