5. 510(k) SUMMARY

APPLICANT: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9512
610-266-0500

Contact: Rebecca A. Stolarick, Director, Regulatory Affairs
Phone: 610-596-2536
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DEVICE NAME: CONTIPLEX® Stim Continuous Nerve Block Set

COMMON OR USUAL NAME: Anesthetic Conduction Kit

DEVICE CLASSIFICATION: 21 CFR 868.5140 - Anesthetic Conduction Kit
Class II, Product Code CAZ

PREDICATE DEVICES: Arrow StimuCath Continuous Nerve Block Set 510(k) K030937
PAJUNK GmbH Stimulong Plus Catheter Sets 510(k) K033018

DESCRIPTION: The CONTIPLEX® Stim Continuous Nerve Block Set is a kit that contains a stimulating catheter with a plastic dispensing coil, tuohy needle, sideport valve assembly, catheter connector, ChloraPrep® One-Step, 3 mL Applicator and a Tegaderm® Transparent Dressing. The catheter is electrically conductive and is composed of an inner metal coil and outer polyamide layer. The catheter is radiopaque and is contained in a plastic dispensing coil with an electrical connector attached to a stylet. The tuohy needle is insulated and has an attached integrated wire. The sideport valve assembly is used in the procedure to attach to the tuohy needle and a syringe containing the anesthetic solution. The Chloraprep (Mediflex) is used to prep the patient's skin prior to the procedure and the Tegaderm (3M) is a dressing.
The CONTIPLEX® Stim Continuous Nerve Block Set is intended for use with B. Braun Stimuplex HNS 11, Stimuplex HNS 12, and Stimuplex Dig RC nerve stimulators. When used with the

Stimuplex HNS 11 and Stimuplex HNS 12 nerve stimulators, the Stimuplex Switch may be used. When used with the Stimuplex Dig RC nerve stimulator, the Stimuplex Switch can not be used.

INTENDED USE: The CONTIPLEX® Stim Continuous Nerve Block Set is intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and/or analgesics near a nerve for regional anesthesia and pain management during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. Routes of administration are perineural (peripheral nerve block). The Contiplex catheter can be used for up to 72 hours.

SUBSTANTIAL EQUIVALENCE: The CONTIPLEX® Stim Continuous Nerve Block Set is substantially equivalent to the predicate devices identified in this 510(k); the Arrow Stimucath device and the PAJUNK Stimulong device. The proposed CONTIPLEX® Stim Continuous Nerve Block Set and the predicate devices have the same indications for use, to delivery anesthetics in epidural and nerve block procedures. The accuracy of delivery of anesthetic agents for the proposed device and predicate devices is facilitated by using an electrically conductive nerve stimulating catheter. The proposed device has been subjected to biocompatibility testing to support the safety of the materials. The proposed device was also subjected to functional performance testing to support that it functions as intended. In addition, the predicate devices were subjected to some of the same functional performance tests for comparison. The results of the comparison testing support the substantial equivalence of the proposed device and the predicate devices. The proposed device and predicate devices have similar technological characteristics. The product design, material composition and performance of the proposed device are similar to those of the predicate devices. The comparison table of the proposed device and predicate devices provided in the 510(k) provides the details of the similarities and differences. Although there are some differences, these differences do 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

Ms. Rebecca A. Stolarick
Director, Regulatory Affairs
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

JUN 20 2007

Re: K063282
Trade/Device Name: CONTIPLEX® Stim Continuous Nerve Block Set
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: June 7, 2007
Received: June 11, 2007

Dear Ms. Stolarick:

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 (240) 276-3150 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

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063282

Device Name: CONTIPLEX® Stim Continuous Nerve Block Set

Indications for Use:

The CONTIPLEX® Stim Continuous Nerve Block Set is intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics near a nerve for regional anesthesia and/or pain management during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. Routes of administration are perineural (peripheral nerve block). The CONTIPLEX® catheter can be used for up to 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)

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

6/19/07

K063282

CONFIDENTIAL

510(k) Number: K063282