K090995

5. 510(k) SUMMARY

AUG 14 2009

SUBMITTER:

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

Contact: Lisa Giaquinto, Sr. Analyst, Regulatory Affairs
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DEVICE NAME:

Contiplex Continuous® Nerve Block Set

COMMON OR USUAL NAME:

Anesthesia Conduction Kit

DEVICE CLASSIFICATION:

Class II, Product Code CAZ, 868.5140

PREDICATE DEVICES:

Contiplex® Stim Continuous Nerve Block Set, B. Braun Medical, Inc., K063282, class II, CAZ, 868.5140

DESCRIPTION:

The Contiplex® Continuous Nerve Block Set consists of an 18 gauge insulated needle, a sideport valve assembly, a 20 gauge polyamide catheter with threading assist guide, and a clamp style catheter connector. The set is used to facilitate the continuous delivery of anesthetics or analgesics through a catheter during regional anesthesia and pain therapy procedures. The Contiplex® insulated 18G needles contained in each set are available in four different lengths with a Tuohy shaped tip, and three different lengths with a straight tip. The needles are designed for precise localization of a nerve by transferring electrical impulses through a thinly coated stainless steel tip.

The Contiplex® needles can be used with the Stimuplex® DIG, the Stimuplex® DIG RC Nerve Stimulator, or the Stimuplex® HNS 11 and HNS 12 Nerve Stimulators.

INTENDED USE:

The B. Braun Contiplex® 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 perineural anesthesia and pain management during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. The route of administration is perineural (peripheral nerve block). The Contiplex® Catheter may remain indwelling for up to 72 hours.

SUBSTANTIAL EQUIVALENCE:

The Contiplex® Continuous Nerve Block Set has the same intended use and contains similar components as the Contiplex® Stim Continuous Nerve Block Set (K063282). Both sets utilize insulated stimulating needles to locate by stimulation, targeted nerve bundles, in order to perform peripheral nerve block procedures. Biocompatibility and functional performance testing have been completed to verify there are no differences between the proposed and predicate device, which raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Lisa Giaquinto
Senior Analyst, Regulatory Affairs
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

AUG 1 4 2009

Re: K090995
Trade/Device Name: B. Braun Contiplex ® Continuous Nerve Block Set
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: August 3, 2009
Received: August 6, 2009

Dear Ms. Giaquinto:

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 Division 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): K090995

Device Name: B. Braun Contiplex® Continuous Nerve Block Set

Indications For Use:

The B. Braun Contiplex® 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 perineural anesthesia and pain management during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. The route of administration is perineural (peripheral nerve block). The Contiplex Catheter may remain indwelling 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)

L Schultz

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

510(k) Number: K090995