JAN 24 2012

5. 510(k) SUMMARY

K 113059

SUBMITTER:

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

Contact: Lisa Giaquinto, Specialist, Regulatory Affairs
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DEVICE NAME: Contiplex® FX Continuous Nerve Block Set

COMMON OR USUAL NAME: Anesthesia Conduction Kit

DEVICE CLASSIFICATION: Class II, Product Code CAZ, 868.5140

PREDICATE DEVICES: Contiplex® Continuous Nerve Block Set, Braun Medical Inc., K090995, Class II, CAZ, 868.5140.

DESCRIPTION: The **B. Braun Contiplex FX Continuous Nerve Block Set** consists of one 17 gauge Tuohy needle, one 19 gauge springwound catheter with threading assist guide, one sideport valve assembly, and one clamp style catheter connector. The set is used to facilitate the continuous delivery of anesthetics or analgesics to the patient for pain management during regional anesthesia procedures.

INTENDED USE: The B. Braun Contiplex® FX Continuous Nerve Block Set is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management. The Contiplex FX catheter may remain indwelling for up to 72 hours.

SUBSTANTIAL EQUIVALENCE: The Contiplex® FX Continuous Nerve Block Set has the same intended use and contains similar components as the Contiplex® Continuous Nerve Block Set cleared under premarket notification # K090995. Both sets include a Tuohy needle, catheter with threading assist guide, sideport valve assembly, and clamp style catheter connector. The primary differences between the proposed Contiplex FX Continuous Nerve Block Set and the predicate Contiplex

Continuous Nerve Block Set relate to the Tuohy needle and catheter. The predicate device contains a coated, stimulating Tuohy needle, while the proposed device contains an uncoated, non-stimulating Tuohy needle. Additionally, the predicate device also includes a polyamide catheter, while the proposed device includes a polyamide catheter with inner springwound coil.

Biocompatibility and functional performance testing have been completed with the proposed Tuohy needle and springwound catheter to verify there are no differences between the proposed and predicate device, which would raise new issues of safety or effectiveness.

Performance Testing

The following performance standards have been utilized in the evaluation of the Tuohy needle included in the proposed Contiplex FX Continuous Nerve Block Set:

ISO 9626: "Stainless steel needle tubing for the manufacture of medical devices."

ISO 7864: "Sterile hypodermic needles for single use."

ISO 594-1: "Conical Fittings with a 6 % Luer taper for syringes, needles and certain other medical equipment – Part 1: General Requirements."

ISO 594-2: "Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings."

The following performance standards has been utilized in the evaluation of the springwound catheter included in the proposed Contiplex FX Continuous Nerve Block Set:

EN 1618: "Catheters Other Than Intravascular Catheters – Test Methods for Common Properties."

Results of performance testing indicate that the needle and catheter in the Contiplex FX Continuous Nerve Block Set meet applicable sections of the standards referenced and are safe and effective for their intended use.

Biocompatibility

Biocompatibiltiy testing was performed based on the nature and duration of patient contact outlined in *ISO 10993-1:"Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* Results of testing demonstrates that the materials used in the construction of the needle and catheter in the proposed Contiplex FX Continuous Nerve Block Set are safe for their intended use.

Conclusion

Based on the results of performance and biocompatibility testing, the proposed nerve block set is considered similar to the predicate device identified above, and is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lisa Giaquinto
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

JAN 2 4 2012

Re: K113059
Trade/Device Name: Contiplex FX Continuous Nerve Block Set
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: December 20, 2011
Received: December 21, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 Names:

Contiplex FX Continuous Nerve Block Set

Indications For Use:

The B. Braun Contiplex® FX Continuous Nerve Block Set is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management. The Contiplex FX 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 Schultheiss

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

510(k) Number: K113059