K121846

5. 510(k) SUMMARY

DATE: November 20, 2012

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SUBMITTER:

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

Contact: Nancy Skocypec, Regulatory Affairs Specialist
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DEVICE NAME: Contiplex® C Continuous Peripheral Nerve Block Needle

COMMON NAME: Peripheral Nerve Block Needle

DEVICE CLASSIFICATION: Needles, Conduction, Anesthetic, W/Wo introducer (21 CFR 868.5150, Product Code BSP)

PREDICATE DEVICE: Contiplex D Insulated Needle, Stimuplex D Insulated Needle
B. Braun Medical, Inc., Contiplex D Continuous Nerve Block Set, K100241, Class II, BSP, 868.5150

DESCRIPTION: The Contiplex C Continuous Peripheral Nerve Block Needle is a needle comprised of an open tip catheter over an insulated needle with a positioning component, a needle hub with integrated injection tubing and cable, and connection tubing.

INTENDED USE: The Contiplex C Continuous Peripheral Nerve Block Needle is intended for use in regional anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator or by ultrasound visualization of the device. The needle is used to inject and facilitate the continuous administration of local anesthetics or analgesics to the targeted nerve bundle in general and orthopedic surgery.

In set configuration, the B. Braun Contiplex C Continuous Peripheral Nerve Block Set, consisting of the peripheral nerve block needle, catheter, and related peripheral nerve block procedural accessories, is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management during pre-operative, perioperative

and post-operative periods associated with general and orthopedic surgery. The catheter may remain indwelling for up to 72 hours.

SUBSTANTIAL EQUIVALENCE:

Technological Characteristics

The Contiplex C Continuous Peripheral Nerve Block Needle has the same intended use as the Contiplex D Insulated Needle (K100241). The proposed device and predicate device both incorporate insulated needles to locate by stimulation, targeted nerve bundles, in order to perform peripheral nerve block procedures. Both devices are advanced toward the target nerve with direction being guided by stimulation and both are used to place an in-dwelling catheter in position local to the target nerve. Both devices include a catheter over needle design.

The primary difference between the proposed Contiplex C Continuous Peripheral Nerve Block Needle and the predicate Contiplex D Insulated Needle relate to the in-dwelling catheter over needle assembly and the resultant methodology used to place the open tip catheter at the targeted nerve bundle. As a result, the needle and catheter dimensions are different from those of the predicate device. Additional differences include connection tubing, needle coating material, catheter material and the option to utilize ultrasound as a placement guide.

Performance Data

Testing was performed with the Contiplex C Continuous Peripheral Nerve Block Needle to support substantial equivalence to the predicate device. Testing included biocompatibility and performance testing.

Biocompatibility testing was performed based on the nature and duration of patient contact in accordance with ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. The insulated needle components were tested per the ISO 10993-1 requirements for an externally communicating device with tissue contact for a limited duration (< 24 hours). The catheter and the connection tubing with adaptors were tested per the requirements of ISO 10993-1 as an externally communicating device with tissue contact for a prolonged duration (> 24 hours, < 30 days). Test results met the acceptance criteria according to ISO 10993.

Performance testing completed included the following functional tests: electrical performance, flow rate, occlusion, kink resistance, bending stability, resistance to breakage, joint bond strength, leakage, simulated use.

The following standards were utilized in the evaluation.

ISO 594-1, *Conical fittings with 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.*

ISO 7864, *Sterile hypodermic needles for single use.*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices.*

EN 13868, *Catheters - Test methods for kinking of single lumen catheters and medical tubing.*

Results of performance testing demonstrate that the Contiplex C Continuous Peripheral Nerve Block Needle meets applicable sections of the standards referenced, performs similarly to the predicate device and can be used safely and effectively according to it's intended use.

CONCLUSION:

Based on the results of biocompatibility and performance testing, the proposed Contiplex C Continuous Peripheral Nerve Block Needle is considered substantially equivalent to the predicate device 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 Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

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

Re: K121846
Trade/Device Name: Complex® C Continuous Peripheral Nerve Block Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: October 26, 2012
Received: October 31, 2012

Dear Ms. Skocypec:

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,

Kwame O. Ulmer

Digitally signed by Kwame O. Ulmer
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=1300183618
Date: 2012.11.20 15:43:01 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, 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): K121846

Device Name: Contiplex® C Continuous Peripheral Nerve Block Needle

Indications For Use:

The Contiplex C Continuous Peripheral Nerve Block Needle is intended for use in regional anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator or through ultrasound visualization of the device. The needle is used to inject and facilitate the continuous administration of local anesthetics or analgesics to the targeted nerve bundle for general and orthopedic surgery.

The Contiplex C Continuous Peripheral Nerve Block Set, consisting of the peripheral nerve block needle, catheter, and related peripheral nerve block procedural accessories, is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management during pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. The 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) Kwame O. Ulmer

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

510(k) Number: