April 13, 2010

K100241

5. 510(k) SUMMARY

SUBMITTER:

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

APR 16 2010

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

Contiplex® D Insulated Needles
Stimuplex® D Insulated Needles
Stimuplex® D Plus Insulated Echogenic Needles

COMMON OR USUAL NAME:

Needles, Conduction, Anesthetic (W/Wo Introducer)

DEVICE CLASSIFICATION:

Class II, Product Code BSP 868.5150

PREDICATE DEVICES:

Contiplex® Continuous Nerve Block Set, B. Braun Medical, Inc., K090995, Class II, CAZ, 868.5140 (containing Contiplex Tuohy and Straight Needle components, Class II, BSP 868.5150)

EchoStim® Facet Tip, Havel, Inc., K063380, Class II, BSP, 868.5150

DESCRIPTION:

The **Contiplex® D Insulated Needles** are intended for locating by stimulation, peripheral nerves for the administration of anesthetic or analgesic fluid to the targeted nerve. The Contiplex D needle includes an introducer catheter over the needle to facilitate the advancement of an indwelling catheter. The dielectric needle coating and electrical connection within the hub facilitate the transfer of electrical impulses from a nerve stimulator to the tip of the needle. The needle hubs include an aspiration or injection tubing line in order to facilitate the initial injection of anesthetic or analgesic fluid as well as a connecting cable, which can be attached to the cables of any of the B. Braun Nerve Stimulators listed on the product labeling. The Contiplex D needle/catheter assemblies will be available in two lengths, gauges and bevel geometries.

The **Contiplex D Insulated Needles** will be available in a set configuration containing one Contiplex D introducer catheter over insulated nerve stimulating needle, one polyamide open-tip catheter with threading assist guide, and one clamp style catheter connector. After needle removal, the short introducer catheter is used to thread a longer open-tip polyamide catheter into the patient. The polyamide catheter and catheter connector are used to administer the continuous flow of anesthetic or analgesic fluid to the patient for up to 72 hours.

The **Stimuplex® D Insulated Needles** are individually packaged insulated needles, intended for the localization and stimulation of peripheral nerve bundles for "single shot" anesthesia. The Stimuplex D needle hubs, like the Contiplex D needles, include an aspiration or injection tubing line in order to facilitate the injection of anesthetic or analgesic fluid. The dielectric needle coating and electrical connection within the hub facilitate the transfer of electrical impulses from a nerve stimulator to the tip of the needle. The Stimuplex D needles can be used with any of the B. Braun Nerve Stimulators listed on the product labeling. The needles will be available in various lengths and gauge sizes with two bevel angles for some sizes.

The **Stimuplex® D Plus Insulated Echogenic Needles** are designed to provide the clinician with two modalities to locate peripheral nerves for nerve block procedures; through electrical stimulation and ultrasound imaging. The dielectric coating and electrical connection within the hub facilitate the transfer of electrical impulses from a nerve stimulator to the tip of the needle. The Stimuplex D Plus needles can be used with any of the B. Braun Nerve Stimulators listed on the product labeling. In addition, the needles are designed with etched markings to help reflect an image of the needle when using an ultrasound imaging machine. Once the nerve is located, the Stimuplex D Plus needles include a tubing line in order to permit the 'single shot' injection of local anesthetic fluid to the nerve. The needles will be available in various lengths and gauge sizes.

INTENDED USE:

The **B. Braun Contiplex® D Insulated Needle** is intended for use in regional anesthesia and pain therapy to locate, by stimulation, peripheral nerves by transferring electrical impulses from a nerve stimulator. 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 D 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 during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. The Contiplex D polyamide catheter may remain indwelling for up to 72 hours.

The B. Braun **Stimuplex® D Insulated Needle** is intended for use in regional anesthesia and pain therapy to locate by stimulation peripheral nerves by transferring electrical impulses from a nerve stimulator. The needle is used to inject a single dose of anesthetic or analgesic fluid to the targeted nerve bundle for general and orthopedic surgery.

The B. Braun **Stimuplex® D Plus Insulated Echogenic Needle** is intended for use in regional anesthesia and pain therapy to target peripheral nerves by transferring electrical impulses from a nerve stimulator and by visualization of an echogenic reflective pattern at the needle tip using an ultrasound imaging device. The needle is used to inject a single dose of anesthetic or analgesic fluid to the targeted nerve bundle for general and orthopedic surgery.

SUBSTANTIAL EQUIVALENCE:

The Contiplex® D Insulated Needles, Stimuplex® D Insulated Needles and Stimuplex® D Plus Insulated Echogenic Needles have the same intended use and are similar in design to the Contiplex Tuohy and Straight needles included in the Contiplex® Continuous Nerve Block Set (K090995). The proposed devices and predicate device incorporate insulated stimulating needles to locate by stimulation, targeted nerve bundles, in order to perform peripheral nerve block procedures. Biocompatibility testing was completed to address any differences in materials and to verify that no new issues of safety have been introduced with the proposed devices. Additionally, performance testing was completed to verify that all design input requirements of the proposed devices have been met. The following performance standards were considered in evaluating the performance of the proposed devices: ISO 9626:1991/Amd. 1:2001(E) "Stainless steel needle tubing for the manufacture of medical devices." ISO 7864:1993(E) "Sterile hypodermic needles for single use." ISO 594-2:1998 "Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings." The results of biocompatibility and performance testing demonstrate the proposed devices raise no new issues of safety or effectiveness when compared to the predicate device.

The Stimuplex D Plus Insulated Echogenic Needles also have similar indications and technological characteristics as Havel Inc.'s EchoStim® needles. Both the proposed needles and predicate needles are indicated for locating by stimulation,

targeted nerve bundles, in order to perform peripheral nerve block procedures. In addition, both the Stimuplex D Plus needles and the EchoStim® needles incorporate etched markings near the needle tip, which help the needles to be visualized under ultrasound. A comparative evaluation of the needles under ultrasound was completed to demonstrate there are no differences between the proposed and predicate device, which raise new issues of safety or effectiveness.

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

APR 1 6 2010

Re: K100241
Trade/Device Name: Stimuplex D Plus Insulated Echogenic Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: January 21, 2010
Received: January 27, 2010

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 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Names: Stimuplex® D Plus Insulated Echogenic Needle

Indications For Use:

The B. Braun **Stimuplex® D Plus Insulated Echogenic Needle** is intended for use in regional anesthesia and pain therapy to target peripheral nerves by transferring electrical impulses from a nerve stimulator and for visualization of an echogenic reflective pattern at the needle tip using an ultrasound imaging device. The needle is used to inject a single dose of local anesthetic or analgesic to the targeted nerve bundle for general and orthopedic surgery.

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: K100241

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Names: Stimuplex® D Insulated Needle

Indications For Use:

The B. Braun **Stimuplex® D Insulated Needle** is intended for use in regional anesthesia and pain therapy to locate by stimulation peripheral nerves by transferring electrical impulses from a nerve stimulator. The needle is used to inject a single dose of local anesthetic or analgesic to the targeted nerve bundle for general and orthopedic surgery.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K100241

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100241

Device Names: Contiplex® D Insulated Needles

Indications For Use:

The B. Braun **Contiplex® D Insulated Needle** is intended for use in regional anesthesia and pain therapy to locate, by stimulation, peripheral nerves by transferring electrical impulses from a nerve stimulator. 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 D 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 during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. The Contiplex D polyamide indwelling 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)

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

510(k) Number: K100241