DEC 2 2 2011

5. 510(k) SUMMARY

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: Pencan Spinal Needles, Spinocan Spinal Needles, Spinal Introducer Needles

COMMON OR USUAL NAME: Needle, Conduction, Anesthetic (W/Wo Introducer)

DEVICE CLASSIFICATION: Class II, Product Code BSP, 21 CFR 868.5150

PREDICATE DEVICES: Pencil Point Spinal Needle, B. Braun Medical Inc., K932569, Class II, BSP, 868.5150.
Spinocan Spinal Needle, B. Braun Medical Inc., K820047, Class II, BSP, 868.5150
Ballpen Spinal Needle, RUSCH INTL, K011122, Class II, BSP, 868.5150

DESCRIPTION: The **B. Braun Pencan Spinal Needle** consists of a polycarbonate hub bonded to a stainless steel cannula with pencil-point tip. The hub of the Pencan spinal needle incorporates a viewing window for visualization of cerebrospinal fluid. The needles are provided with a stylet with color-coded hub that corresponds to the needle gauge. The needles will be offered in gauges ranging from 22 Ga. to 27 Ga. Needles that are 24 Ga.-27 Ga. may be used with an individually packaged 20 Ga. or 22 Ga. introducer needle.

The **B. Braun Spinocan Spinal Needle** consists of the same polycarbonate hub as the Pencan needles. The hub is bonded to a stainless steel cannula with Quincke bevel. The needles are provided with a stylet with color-coded hub that corresponds to the

needle gauge. The needles will be offered in gauges ranging from 18 Ga. to 27 Ga. Needles that are 25 Ga. – 27 Ga. may be used with an individually packaged 20 Ga. or 22 Ga. introducer needle.

INTENDED USE:

The Pencan spinal needles with or without introducer are intended for the injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management or to facilitate CSF sample collection for diagnostic purposes (lumbar puncture). The needles are intended for use in any target population with consideration given to the anatomy of the patient.

The Spinocan spinal needles with or without introducer are intended for the injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management or to facilitate CSF sample collection for diagnostic purposes (lumbar puncture). The needles are intended for use in any target population with consideration given to the anatomy of the patient.

SUBSTANTIAL EQUIVALENCE:

The proposed B. Braun Pencan spinal needles and spinal introducer needles are similar to the Pencan spinal needles and introducer needle included in cleared premarket notification # K932569. Both the proposed Pencan spinal needles and predicate needles incorporate the same needle cannula and pencil point tip design. The primary differences between the proposed Pencan spinal needles and spinal introducer needles when compared to the predicate devices are the geometric shape of the needle hubs, non-solution contacting materials and additional needle gauges and lengths.

Similarly, the proposed Spinocan spinal needles are similar to the Spinocan spinal needles cleared under premarket notification # K820047. Both the proposed Spinocan needles and predicate device have the same intended use, and incorporate the same needle cannula, and Quincke tip design. The primary differences between the proposed Spinocan needles and the predicate Spinocan needles is the needle hub geometry, non-solution contacting materials and additional needle gauges and lengths.

The proposed Pencan and Spinocan spinal needles are also similar in intended use and needle dimensions to the BallPen Spinostar Spinal needles marketed by Teleflex Medical under premarket

notification # K011122. The proposed needles and BallPen spinal needles are similar in needle and stylet design and may be used with a corresponding introducer needle.

Performance Testing

The following performance standards have been utilized in the evaluation of the proposed Pencan and Spinocan spinal needles and spinal introducer needles:

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 594-1:1986, "Conical Fittings with a 6 % Luer taper for syringes, needles and certain other medical equipment – Part1: General Requirements."

ISO 594-2:1998 "Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings."

Results of performance testing indicate that the needles meet applicable sections of the standards referenced and are safe and effective for their intended use.

Biocompatibility

Biocompatibiltiy testing based on the nature and duration of patient contact outlined in *ISO 10993-1:2009 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* demonstrates that the materials used in the construction of the proposed needles are safe for their intended use.

Conclusion

Based on the indications for use and results of performance and biocompatibility testing, the proposed needles are considered similar to the predicate devices identified above, and are safe and effective for their 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
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Allentown, Pennsylvania 18109-9341

DEC 2 2 2011

Re: K112515
Trade/Device Name: Pencan Spinal Needle, Spinocan Spinal Needle, Spinal Introducer Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Needle, Conduction, Anesthetic (W/Wo Introducer)
Regulatory Class: II
Product Code: BSP
Dated: December 19, 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,

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:

Pencan Spinal Needle, Spinocan Spinal Needle, Spinal Introducer Needle

Indications For Use:

The Pencan spinal needles with or without introducer are intended for the injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management or to facilitate CSF sample collection for diagnostic purposes (lumbar puncture). The needles are intended for use in any target population with consideration given to the anatomy of the patient.

The Spinocan spinal needles with or without introducer are intended for the injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management or to facilitate CSF sample collection for diagnostic purposes (lumbar puncture). The needles are intended for use in any target population with consideration given to the anatomy of the patient.

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 Achutta

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

510(k) Number: K112515