K120475

DEC 2 1 2012

Section 3 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date of Submission:

Submitted by:
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Device Name:
Trade Names: AN-SI spinal needle,AN-SII spinal needle,AN-E epidural needle
Common Names: Anesthesia conduction needles

Classification Name: Anesthesia conduction needles

Regulation Number: 21 CFR 868.5150

Product Class: Class II

Product Code: BSP

Preparation Date of Summary: Now 30, 2011

Predicate Device: IMD's Tuohy needle; Quincke needle; Pencil Point needle (K 070354)

Device Description:
Anesthesia conduction needles, including Epidural Needle for Single Use(AN-E), Spinal Needle for Single Use(AN-SI,

AN-SII), consist of needle tube, hub, stylet and jacket The product is mainly used for epidural and/or spinal block (also called as epidural and/or spinal anesthesia) in human bodies.

The needles have been categorized as following in detail:

1. AN-SI Spinal Needles (same to IMD's Quincke needle)
2. AN-SII Spinal Needle (same to IMD's Pencil point needle)
3. AN-E Epidural Needles (same to IMD's Tuohy needle)

These needles are provided as sterile, single use devices. They may be packaged individually or included in regional anesthesia trays (kits). Anesthesia conduction needles fit into an introducer needle. This is a simple hypodermic needle to make the initial puncture through the skin to aid in the placement of the anesthesia conduction needle. The later can facilitate the placement of an epidural catheter for continuous infusion of local anesthetics into the epidural space for longer pain relief.

The Shanghai SA's anesthesia conduction needles – AN-SI, AN-SII, AN-E – are single use, sterile medical devices for transient delivery of anesthetics during regional anesthesia. The cannula is stabilized during puncture with use of an inner stylet. This stylet is withdrawn after the anesthesia conduction needle has reached its anatomical site for regional anesthesia. Then the anesthetics can be applied transiently (i.e., within minutes) by the professional anesthetist. Alternatively or additionally, an epidural catheter may be placed through the anesthesia conduction needle. The needle is withdrawn and the epidural catheter tip may remain in the epidural space for pain treatment.

Intended Use:

Anesthesia conduction needles are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Technology Characteristics:

The Shanghai SA anesthesia conduction needles- AN-E,AN-SI,AN-SII- have the same technological characteristics as the predicate devices identified above. The Shanghai SA anesthesia conduction needles- AN-E,AN-SI,AN-SII- are equivalent in design physical dimensions, luer hub, metal and plastic materials, and packaging to the IMD anesthesia needle cleared under 510(K) number K070354

The Anesthesia Conduction Needles general design characteristics and functionality are similar in that they meet performance standards where applicable for:

Stainless Steel components: ISO 9626
Hub: ISO 594-1 and ISO 594-2
Hub to Needle Bond Strength: ISO 7864

All statements and representations set forth herein regarding or related to "substantially equivalent" or "substantial equivalence" are in the limited context of the definition and purpose of substantial equivalence in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations of the Food and Drug Administration, and are not made in the context of, for any purpose related to, or as an admission against interest under, any other laws or regulations, including

patent laws (whether in the context of patent infringement or otherwise).

Nonclinical testing Conclusion:

Performance testing was conducted to validate and verify that the proposed device met all design specifications and was substantially equivalent to the predicate device:

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 – Part 1:General Requirements."

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

Sterilization is equivalent to predicate device since the materials, packaging, and sterilization processed are the same.

SE Conclusion:

The comparison between the predicate devices and the proposed devices demonstrates that the proposed devices are safe and effective, as well as substantially equivalent to the predicate devices. Anesthesia conduction needles can be claimed to be Substantially Equivalent (SE) to the predicate device, Predicate Device IMD's Tuohy needle; Quincke needle; Pencil Point needle K 070354.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 21, 2012

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C/O Mike Gu
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Re: K120475
Trade/Device Name: Anesthesia Conduction Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: December 12, 2012
Received: December 12, 2012

Dear Mr. Gu:

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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indication for Use Statement

510(k) Number: K120475

Device Name: Anesthesia conduction needles

Indications for Use:

Anesthesia conduction needles are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neel J. Patel

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

510(k) Number: K120475