



Traditional 510(k) Premarket Notification\_Anesthesia conduction needles

### 510(k) Summary

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92 the following summary of information is provided:

**Date:** April 7, 2013

**Submitter:** LCCS Products Limited  
Add: FLAT 1801A ,18/F., ON HONG COMMERCIAL BLDG, 145 HENNESSY ROAD, WANCHAI, HONGKONG

**Primary Contact Person:** Mike Gu  
Regulatory Affairs Manager  
OSMUNDA Medical Device Consulting Co., Ltd.  
Tel: (+86) 20-6232 1333  
Fax: (+86) 20-8633 0253  
Email: mike.gu@osmundacn.com

**Secondary Contact Person:** Mrs. Elizabeth Ma  
Vice President  
LCCS Products Limited  
Tel: +852-81368758  
Fax: + 852-35430978  
Email: lccsmed@126.com

**Device:** **Trade Name:** AN-SI spinal needle, AN-SII spinal needle, AN-E epidural needle  
**Common/Usual Name:** Anesthesia conduction needles

**Classification Names:** Needle, Conduction, Anesthetic (W/Wo Introducer)

**Product Code:** BSP

**Classification:** II

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

**Device Description:** The proposed device, Anesthesia conduction needles, including Epidural Needle for Single Use (AN-E), Spinal Needle for Single Use (AN-SI, AN-SII) was developed by LCCS Products Limited to meet urgent demands on prevention of cross- infection.

Anesthesia conduction needles, is a kind of sterile and sharp hollow-device used for transferring anaesthetic to epidural cavities. The device can be used for introducing dedicated ducts into epidural cavities for convenience of injecting anaesthetic continuously. 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.

The needle tubing 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 This stylet is withdrawn after the anesthesia conduction needle has reached its anatomical site for neuraxial anesthesia.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 The needle is withdrawn and the epidural catheter tip may remain in the epidural space for pain treatment. The stylet hub is made of HDPE, the needle hub is made of resin, the raw material of the needle tubing and stylet is stainless steel, the jacket is PP, all the raw materials are biocompatible.

Intended Use:

AN-E epidural needle is intended for the transient delivery of anesthetics to provide neuraxial anesthesia or to facilitate placement of an epidural catheter.

AN-SI spinal needle and AN-SII spinal needle are intended for the transient delivery of anesthetics to provide neuraxial anesthesia.



**Technology characteristic :** The diameters of the AN-SI, AN-II and AN-E are 20g-27g, 22g-27g and 15g-20g successively, the diameters of the needles of this 510k submission are similar to the diameters of the cannulas covered by the predicate devices. Plus the properties of stiffness and resistance to breakage are tested and the results are in the criteria of the ISO 9626.

The lengths of the AN-SI, AN-II and AN-E are 25mm-200mm, 60mm-200mm and 50mm-150mm successively, different lengths used for different group of patient, for example an obese patient use a longer needle, and also the choose of length depends on the target site of the clinical application.

The Anesthesia Conduction Needles' (AN-E, AN-SI, AN-SII) general design characteristics and functionality met performance standards requirements where applicable for:

Stainless Steel components: ISO 9626

Hub: ISO 594-1 and ISO 594-2

Hub to Needle Bond Strength: ISO 7864

Tip specifications: the tips of the needles are identical to the tips of the predicate devices.

Diameter: the diameters of the needles of this 510k submission are similar to the diameters of the cannulas covered by the predicate devices. Plus the properties of stiffness and resistance to breakage are tested and the results are in the criteria of the ISO 9626.

Length: the lengths of the needles of this 510k submission are different as compared to the lengths of the needles in the predicate device needles. Different lengths used in different group of patient, it depends on the target site of the clinical application.

Each size of the needles is tested following the ISO 9626, the test results show that each size of the needles meets the criteria of the standard. The results of the test of resistance to breakage show the needles of each size meet the standard requirements.

**Determination of Substantial Equivalence:**

**Summary of Non-Clinical Tests**

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% (Luer) taper for syringes, needles and certain other medical equipment- Part 2:

Lock fittings. "

Each size of the needles is tested following the ISO 9626, the test results show that each size of the needles meets the criteria of the standard. The results of the test of resistance to breakage show the needles of each size meet the requirements.

Results of performance testing indicate that the needles meet applicable sections of the standards referenced.

Please refer to the appendix A performance test report, please refer to the appendix B1 AN-E biocompatibility test and appendix B2 AN-SI biocompatibility test

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

The AN-E, each size of AN-SI and AN-SII is composed of the same raw material, each size of AN-E is composed of the same raw material, as well as the AN-SI, AN-SII and AN-E needles have the identical type and duration of patient contact. Additionally, Anesthesia conduction needles are processed using the identical manufacturing methods as the IMD's Tuohy needle; Quincke needle; Pencil Point needle

The following is the specification, Length and diameter comparison between the proposed device and predicate device:



Table 12-2 Specifications

Parameters	Proposed Device			Predicate Device		
	AN-E	AN-SI	AN-SII	Tuohy needle	Quincke needle	Pencil Point needle
Specification	20G(0.9) 19G(1.1) 18G(1.2) 17G(1.4) 16G(1.6) 15G(1.8)	27G(0.4) 26G(0.45) 25G(0.5) 24G(0.55) 23G(0.6) 22G(0.7) 21G(0.8) 20G(0.9)	27G(0.4) 26G(0.45) 25G(0.5) 24G(0.55) 23G(0.63) 22G(0.7)	20G(0.9), 18G(1.2), 17G(1.4), 16G(1.6), 15G(1.8)	27G(0.4), 26G(0.45), 25G(0.5), 24G(0.55), 23G(0.6), 22G(0.7), 21G(0.8), 20G(0.9), 19G(1.1), 18G(1.2), 17G(1.4), 16G(1.6)	27G(0.4), 26G(0.45), 25G(0.5), 24G(0.55), 23G(0.6), 22G(0.7), 21G(0.8), 20G(0.9)
Length	50-150	25-200	60-200	35, 40, 45, 55, 57, 75, 80, 85, 90, 125	25~120	25~120
Diameter	0.70 0.80 0.90 1.10 1.20 1.50 1.60 1.80	0.40 0.45 0.50 0.55 0.60 0.70 0.80 0.90	0.40 0.45 0.50 0.55 0.63 0.7	0.90, 1.29, 1.50, 1.65, 1.80	0.42, 0.46, 0.50, 0.55, 0.65, 0.71, 0.81, 0.90, 1.09, 1.25, 1.50,	0.42, 0.46, 0.50, 0.55, 0.65, 0.71, 0.81, 0.90



### Statement of the identical raw materials

LCCS PRODUCTS LIMITED applies 510k application of Anesthesia conduction needles, whose formulation, technical and function characters are the same with the anesthesia conduction needles manufactured by Shanghai SA Medical & Plastic Instruments Co., Ltd, who is the contract manufacturer of the specialty / anesthesia needles - Tuohy, Quincke and Pencil Point Needles produced by INTERNATIONAL MEDICAL DEVELOPMENT, INC.

LCCS's Anesthesia conduction needle 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: Spinal Needle for Single Use (AN-SI Spinal Needles, AN-SII Spinal Needle), and Epidural Needle for Single Use (AN-E Epidural Needles). They consist of five parts: Stylet hub, Needle hub, Needle tubing, Stylet and Jacket; Needle hub, Needle tubing and Stylet contact directly or indirectly with patient, their raw materials are listed in the table below:

Parts	Material
Needle hub	K-Resin KR03
Needle tubing	SUS 304
Stylet	SUS 304

As demanded by IMD, Shanghai SA has manufactured the needle hub using K-Resin KR03 since 2009.

I certify that, in my capacity as Vice General Manager of Shanghai SA Medical & Plastic Instruments Co., Ltd, The raw materials listed above of the Anesthesia conduction needles are identical to the raw materials of the IMD's specialty / anesthesia needles - Tuohy, Quincke and Pencil Point Needles as it was approved in K070354 in formulation, processing, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, micro-release agents, etc.).

I certify that the information above is truthful and accurate and that no material fact has been omitted. Shanghai SA Medical & Plastic Instruments Co., Ltd will bear all legal responsibility if any issue arises.

Signature (Shanghai SA):

Date: 2013.10.24

### Conclusion:

The comparison between the predicate devices and the proposed devices demonstrates that the proposed devices are similar, 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.



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

December 6, 2013

LCCS Products Limited  
C/O Mike Gu  
Regulatory Affairs Manager  
OSMUNDA Medical Device Consulting Co., Ltd.  
Junggui Business Building No. 982, 7th floor  
Congyun Rd., Baiyun District  
Guangzhou, Guangdong  
China 510420

Re: K131006

Trade/Device Name: AN-SI spinal needle, AN-SII spinal needle, AN-E epidural needle  
Regulation Number: 21 CFR 868.5150  
Regulation Name: Anesthesia Conduction Needle  
Regulatory Class: II  
Product Code: BSP  
Dated: November 5, 2013  
Received: November 6, 2013

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.

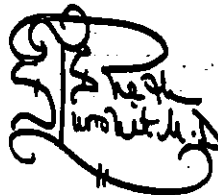
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Tejashri Purohit-Sheth, M.D.  
Clinical Deputy Director  
DAGRID

FOR

Erin I. Keith, M.S.  
Acting Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure





Traditional 510(k) Premarket Notification\_Anesthesia conduction needles

510(k) Number (if known): **K131006**

Device Name: **AN-E epidural needle**

Common/Usual Name: **Anesthesia conduction needles**

Indications for Use:

AN-E epidural needle is intended for the transient delivery of anesthetics to provide neuraxial anesthesia or to facilitate placement of an epidural catheter.

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use   
(Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan J. Patel -S  
2013.12.06 14:08:02 -05'00'