January 5, 2018

Zhejiang kindly Medical Devices Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 China

Re: K171518
Trade/Device Name: Epidural Anesthesia Needles, Spinal Anesthesia Needles, Combined Anesthesia Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: December 11, 2017
Received: December 13, 2017

Dear Diana Hong:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -S
2018.01.05 11:04:19 -05'00'

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K171518

Device Name
Spinal Anesthesia Needles, Epidural Anesthesia Needles, Combined Anesthesia Needles

Indications for Use *(Describe)*
The Epidural Anesthesia Needles are intended to be used for injection into the epidural space/or placing the epidural catheter into the epidural space.

The Spinal Anesthesia Needles are intended to be used for injection of local anesthetic agent into the subarachnoid cavity for pain management.

The Combined Anesthesia Needles are intended for injection of local anesthetics into the spinal and epidural spaces of a patient to provide regional anesthesia. The administration of the spinal anesthesia allows rapid anesthesia onset and the placement of an epidural catheter allows for bolus injections or continuous infusion of local anesthetics or other drugs into the epidural space.

Type of Use *(Select one or both, as applicable)*

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Exhibit #2 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K171518

1. Date of Preparation: 01/02/2017

2. Sponsor Identification

**Zhejiang kindly medical devices Co., Ltd.**
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District,
325025 Wenzhou, Zhejiang Province, PRC.

Establishment Registration Number: Not yet registered

Contact Person: Zenghua Zhang
Position: General Manager
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd**
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Spinal Anesthesia Needles
Epidural Anesthesia Needles
Combined Anesthesia Needles
Common Name: Anesthesia conduction needle

Regulatory Information

Classification Name: Anesthesia conduction needle
Classification: II;
Product Code: BSP;
Regulation Number: 21CFR 868.5150
Review Panel: Anesthesiology

Intended Use Statement:

The Epidural Anesthesia Needles are intended to be used for injection into the epidural space/or placing the epidural catheter into the epidural space.

The Spinal Anesthesia Needles are intended to be used for injection of local anesthetic agent into the subarachnoid cavity for pain management.

The Combined Anesthesia Needles are intended for injection of local anesthetics into the spinal and epidural spaces of a patient to provide regional anesthesia. The administration of the spinal anesthesia allows rapid anesthesia onset and the placement of an epidural catheter allows for bolus injections or continuous infusion of local anesthetics or other drugs into the epidural space.

Device Description

The proposed device, Epidural Anesthesia Needles are available in a series combination of needle size and length. The needle tubing is stabilized during puncture with use of an inner stylet. The stylet is withdrawn after the epidural anesthesia needle has reached its anatomical site for neuraxial anesthesia. Then an epidural catheter is introduced into epidural cavities for convenience of injecting anesthetic continuously.

The proposed device, Spinal Anesthesia Needles are available in a series combination of needle size and length. The spinal anesthesia needle has a tightly fitting removable stylet that completely occludes the lumen to avoid block. The stylet is withdrawn after the spinal anesthesia needle has penetrated into the subarachnoid space for injecting anesthetic. The needles are available in Sprotte and Quincke two type.

The proposed device, Combination Anesthesia Needle are instruments for a spinal (subarachnoid) injection of anesthetics, followed by the placement of an epidural catheter to allow modification of the spinal analgesia if necessary, or continuous infusion of local anesthetics into the epidural space for subsequent pain relief if required. The needles are a matched set. The epidural needle and the spinal needle are locked by conical fitting that enable the spinal needle to be locked into position once the dura has been pierced so that it is secured to the epidural needle to prevent accidental displacement.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K142553
Product Name: Uniever Disposable Epidural Anesthesia Needle

Predicate Device 2
510(k) Number: K141126
Product Name: UNIEVER Disposable Spinal Anesthesia Needle

Predicate Device 3
510(k) Number: K993619
Product Name: CSEcure™ Combined Spinal/Epidural Anesthesia System with Lock

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 9626:1991 AMD 1:2001 Stainless Steel Needle Tubing for the Manufacture of Medical Devices.
- ISO 7864:1993 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
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;
- ASTM F88/88M-09 Standard test method for seal strength of flexible barrier materials;
- ASTM F1140/1140M-13 Standard test methods for internal pressurization failure resistance of

unrestrained packages

- USP38-NF33 <85> Bacterial Endotoxins Test
- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11:2006 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ISO 10993-4: 2002/Amd 1: 2006 Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for Epidural Anesthesia Needles

| Item | Proposed Device | Predicate Device 1<br>K142553 |
|---|---|---|
| Product Code | BSP | Same |
| Regulation Number | 21 CFR 868.5150 | Same |
| Class | II | Same |
| Intended Use | The Epidural Anesthesia Needles are intended to be used for injection into the epidural space/or placing the epidural catheter into the epidural space. | The Uniever Disposable Epidural Anesthesia Needle is intended to be used for injection into the epidural space/or placing the epidural catheter into the epidural space. |
| Configuration | Stylet Hub<br>Stylet<br>Needle Tube<br>Needle Hub<br>Needle Hub Insert<br>Protective Cap of Needle | Stylet Hub<br>Stylet<br>Needle Tube<br>Needle Hub<br>Needle Hub Insert<br>Protective Cap of Needle |
| Needle Gauge | 14G~22G | 14G~25G |
| Needle Length | 65mm, 70mm, 80mm, 90mm, 100mm, 110mm, 120mm, 150mm | 30~160mm |
| Sterile | EO Sterilized | Same |
| | $10^{-6}$ | |
| Single Use | Single Use | Same |
| Needle Tip | Tuohy | Huber, Hustead and Crawford |
| Label/Labeling | Conform with 21 CFR 801 | Same |
| Biocompatibility | | |
| Cytotoxicity | No Cytotoxicity | Conform with ISO 10993 |
| Intracutaneous Reactivity | No Intracutaneous Reactivity | |
| Skin Sensitization | No Sensitization | |
| Acute Systemic Toxicity | No Systemic Toxicity | |
| Hemolysis | No Hemolysis | |
| Pyrogen | No Pyrogen | |

Table 2 Comparison of Technology Characteristics for Spinal Anesthesia Needles

| Item | Proposed Device | Predicate Device 2<br>K141126 |
|---|---|---|
| Product Code | BSP | Same |
| Regulation Number | 21 CFR 868.5150 | Same |
| Class | II | Same |
| Intended Use | The Spinal Anesthesia Needles are intended to be used for injection of local anesthetic agent into the subarachnoid cavity for pain management. | UNIEVER Disposable Spinal Anesthesia Needle is intended to be used for injection of local anesthetic agent into the subarachnoid cavity for pain management. |
| Configuration | Stylet Hub<br>Stylet<br>Needle Tube<br>Needle Hub<br>Needle Hub Insert<br>Protective Cap of Needle<br>Cannula Needle Tube | Stylet Hub<br>Stylet<br>Needle Tube<br>Needle Hub<br>Needle Hub Insert<br>Protective Cap of Needle<br>Cannula Needle Tube |
| Needle Gauge | 18G~27G | 18G~29G |
| Needle Length | 40mm, 50mm, 65mm, 70mm, 80mm, 90mm, 120mm | 30~150mm |
| Sterile | EO Sterilized | Same |
| | $10^{-6}$ | |
| Needle Tip | Quincke and Pencile | Sharp and blunt |
| Single Use | Single Use | Same |
| Label/Labeling | Conform with 21 CFR 801 | Same |
| Biocompatibility | | |
| Cytotoxicity | No Cytotoxicity | Conform with ISO 10993 |
| Intracutaneous Reactivity | No Intracutaneous Reactivity | |
| Skin Sensitization | No Sensitization | |
| Acute Systemic Toxicity | No Systemic Toxicity | |
| Hemolysis | No Hemolysis | |
| Pyrogen | No Pyrogen | |

Table 3 Comparison of Technology Characteristics for Combined Anesthesia Needles

| Item | Proposed Device | | Predicate Device 3<br>K993619 | |
|---|---|---|---|---|
| Product Code | BSP | | Same | |
| Regulation Number | 21 CFR 868.5150 | | Same | |
| Class | II | | Same | |
| Intended Use | The Combined Anesthesia Needles are intended for injection of local anesthetics into the spinal and epidural spaces of a patient to provide regional anesthesia. The administration of the spinal anesthesia allows rapid anesthesia onset and the placement of an epidural catheter allows for bolus injections or continuous infusion of local anesthetics or other drugs into the epidural space. | | The combined spinal epidural needle kit is intended for injection of local anesthetics into the spinal and epidural spaces of a patient to provide regional anesthesia. The administration of the spinal anesthesia allows rapid anesthesia onset and the placement of an epidural catheter allows for bolus injections or continuous infusion of local anesthetics or other drugs into the epidural space. | |
| Configuration | Stylet Hub<br>Stylet<br>Needle Tube<br>Needle Hub<br>Needle Hub Insert<br>Protective Cap of Needle<br>Cannula Needle Tube | | Stylet Hub<br>Stylet<br>Needle Tube<br>Needle Hub<br>Needle Hub Insert<br>Protective Cap of Needle<br>Cannula Needle Tube | |
| Needle Gauge and Length | Epidural Needle | Spinal Needle | Epidural Needle | Spinal Needle |
| | 14G~18G | 22G~27G | 17G, 18G | 26G, 27G |
| | 60~120mm | 110~150mm | 90mm | 132mm |
| Sterile | EO Sterilized | | Same | |
| | $10^{-6}$ | | | |
| Single Use | Single Use | | Same | |
| Label/Labeling | Conform with 21 CFR 801 | | Same | |
| Biocompatibility | | | | |
| Cytotoxicity | No Cytotoxicity | | Conform with ISO 10993 | |
| Intracutaneous Reactivity | No Intracutaneous Reactivity | | | |
| Skin Sensitization | No Sensitization | | | |
| Acute Systemic Toxicity | No Systemic Toxicity | | | |
| Hemolysis | No Hemolysis | | | |
| Pyrogen | No Pyrogen | | | |

From above comparison table, the proposed devices have different combination of needle gauge and needle length compared with predicate devices. However, the different specification will be selected by physician per patient's condition. Therefore, this difference is not considered to affect substantially equivalence.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.