DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 14, 2015

Unisis Corp.
% Ms. Diane Rutherford
Submissions Manager
Ken Block Consulting, Inc.
1201 Richardson Drive
Suite 280
Richardson, Texas 75080-4403

Re: K142553
Trade/Device Name: Uniever Disposable Epidural Anesthesia Needle, Uniever Disposable Nerve Blocked Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: December 12, 2014
Received: December 15, 2014

Dear Ms. Rutherford,

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Erin I. Keith -S

Erin Keith
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142553

Device Name
Uniever Disposable Epidural Anesthesia Needle, Uniever Disposable Nerve Blocked Needle

Indications for Use *(Describe)*

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.

Uniever Disposable Nerve Blockade Needle is intended to be used for injection of local anesthetic agent near the nerve for temporary pain control.

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.

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5. 510(k) SUMMARY

K142553

Submitter:	UNISIS Corp 2675-1, NISHIKATA Koshigaya-shi, Saitama 343-0822 Japan
Contact Person:	Unisis Corp Mr. Tadashi Yasuda Medical Information Department 2623-1, NISHIKATA Koshigaya-shi, Saitama 343-0822 Japan TEL: 048-990-8250 FAX: 048-990-8251 m-info@unisis.co.jp
Date Prepared:	August 28, 2014
Trade Name:	UNIEVER Disposable Epidural Anesthesia Needle UNIEVER Disposable Nerve Blockade Needle
Common Name:	Epidural Anesthesia Needle Nerve Block Needle
Classification Name:	NEEDLE, CONDUCTION, ANESTHETIC (W/WO INTRODUCER)
Product Code:	BSP Class 2 868.5150

Predicate Devices:

* K131006	LCCS	AN-E Epidural Needle
* K040965 K113207	Pajunk	Tuohy needle, Quincke needle, Chiba needle and Crawford needle [Sono]
* K041843	Epimed	Blunt Nerve Block Needle
* K081864	Life-Tech	ProLong Continuous Nerve Block Set

Device Description:

The UNIEVER Disposable Epidural Anesthesia Needles and UNIEVER Disposable Nerve Blockade Needles are available in an array of sizes, lengths, and bevel and tip designs. Both have a tightly fitting removable stylet.

The UNIEVER Disposable Epidural Anesthesia Needles are available with Huber, Hustead, or Crawford tips. Available sizes are 14G to 25G (Huber), 16G to 19G (Hustead), and 16G to 22G (Crawford) for lengths of 30-160mm.

The UNIEVER Disposable Nerve Blockade Needles are available with Back-Cut, K-3, or Huber tips. Available sizes are 18G, 20G to 26G for lengths of 25-260mm (Back Cut and K-3), and 20G, 22G and 25G for lengths of 30-160mm (Huber).

Statement of Intended Use:

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.

UNIEVER Disposable Nerve Blockade Needle is intended to be used for injection of local anesthetic agent near the nerve for temporary pain control.

Summary of Technological Characteristics:

As with the predicates, the UNIEVER Disposable Epidural Anesthesia and UNIEVER Disposable Nerve Blockade Needles are single use, terminally sterilized devices available in various gauge/length combinations including the overall combined ranges of 14G – 26G and 25mm to 260mm. The proposed devices share technological characteristics with the predicate devices. The proposed devices also have some differences in technological characteristics from those of the predicate devices. The differences in the technological characteristics are minor and reflect market strategy and do not impact the safety, effectiveness, or substantial equivalence of the device.

UNIEVER Disposable Epidural Anesthesia Needle offers various needle types as do the predicate devices. The UNIEVER Disposable Epidural Anesthesia Needle and both predicates identify the identical biocompatibility category, contact, and duration. UNIEVER Disposable Epidural Anesthesia Needles as well as both predicates are sterilized using ethylene oxide (EO) with Unisis specifying an SAL of 10^{-6}.

Minor differences do exist between the UNIEVER Disposable Epidural Anesthesia Needle and the predicates. For example, the UNIEVER Disposable Epidural Anesthesia Needles offer a 14G needle while the two predicates have 15G [K110194] or 16G [K112515] as the largest gauge offered. The UNIEVER Disposable Epidural Anesthesia Needles also differ in the minimum and maximum needle lengths offered with the UNIEVER Epidural needles ranging from 30mm – 160mm with the predicates offering 50mm – 150mm [K131006] and 20mm-180mm [K040965, K113207]. All the lengths offered for the UNIEVER Disposable Epidural Anesthesia Needles fall within the ranges offered by the identified predicates.

The UNIEVER Disposable Nerve Blockade Needle various needle types as do the predicate devices. Both the UNIEVER Blockade and the K041843 predicate identify the identical biocompatibility category, contact, and duration. UNIEVER Disposable Nerve Blockade Needles are sterilized using ethylene oxide (EO) to an SAL of 10^{-6}.

Minor differences do exist between the UNIEVER Disposable Nerve Blockade Needle and the predicates. For example, the UNIEVER Disposable Nerve Blockade Needles offer a 26G needle while the two predicates have 25G [K041843] or 20G [K081864] as the smallest gauge offered. The UNIEVER Disposable Nerve Blockade Needles also differ in the minimum and maximum needle lengths offered with the UNIEVER Blockade needles ranging from 25mm – 260mm with the predicates offering 38mm – 203.2mm [K041843] and 25mm – 150 mm [K081864].

As all the needles offered are tested for compliance to the same international standards (ISO 7864 and ISO 9626) this difference does not impact the safety, effectiveness, or substantial equivalence of the device.

Summary of Performance Testing:	Tests were performed on the UNIEVER Disposable Spinal Epidural Anesthesia Needles and the UNIEVER Disposable Nerve Blockade Needles including verification/validation testing to internal functional specifications which demonstrated that the devices are safe and effective. Testing confirmed that the UNIEVER Disposable Spinal Epidural Anesthesia Needles and the UNIEVER Disposable Nerve Blockade Needles comply with relevant voluntary safety standards, specifically ISO standards 594-1, 7864, and 9626. In addition, evaluations and validations have been performed to demonstrate compliance to the applicable standards for biocompatibility (ISO 10993-1) and sterilization including additional endotoxin and particulate testing for CSF contact. Biocompatibility testing performed includes cytotoxicity, sensitization and irritation. Pyrogenicity was also tested.
Conclusion:	*Unisis Corp* considers the *UNIEVER Disposable Epidural Anesthesia Needle and the UNIEVER Disposable Nerve Blockade Needle* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.