DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 31, 2014

Unisis Corp, Inc.
c/o Ms. Diane Rutherford
Submission Manager
Ken Block Consulting
1201 Richardson Dr., Suite #280
Richardson, TX 75080

Re: K141126
Trade/Device Name: UNIEVER Disposable Spinal Anesthesia Needle
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: October 2, 2014
Received: October 3, 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 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" (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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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

Enclosure

INDICATIONS FOR USE

510(k) Number: K141126

Device Name: UNIEVER Disposable Spinal Anesthesia Needle

Indications for Use:

UNIEVER Disposable Spinal Anesthesia Needle is intended to be used for injection of local anesthetic agent into the subarachnoid cavity for pain management.

Prescription Use ____X (21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

5. 510(k) SUMMARY

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:	April 15, 2014
Trade Name:	UNIEVER Disposable Spinal Anesthesia Needle
Common Name:	Spinal Anesthesia Needle
Classification Name:	NEEDLE, CONDUCTION, ANESTHETIC (W/WO INTRODUCER)
Product Code:	BSP Class 2 868.5150
Predicate Device:	K112515 B.Braun Pencan Spinal Needles, Spinocan Spinal Needles, Spinal Introducer Needles K110194 Medline Medline Epidural and Spinal Needles
Device Description:	The UNIEVER Disposable Spinal Anesthesia Needles are available in an array of sizes, lengths, and bevel and tip designs. The UNIEVER Disposable Spinal Anesthesia Needle has a tightly fitting removable stylet that completely occludes the lumen to avoid tracking epithelial cells into the subarachnoid space. The needles are available with a sharp (cutting)-tip or a blunt-tip. UNIEVER Disposable Spinal Anesthesia Needles are also available with an introducer. Available sizes are 18G to 29G (K-3), and 22G to 29G (Pencil Point) for lengths of 30-150mm. The introducers are available in sizes of 18G-22G with needle lengths of 25-50mm.
Statement of Intended Use:	UNIEVER Disposable Spinal Anesthesia Needle is intended to be used for injection of local anesthetic agent into the subarachnoid cavity for pain management.
Summary of Technological Characteristics:	As with the predicates, the UNIEVER Disposable Spinal Anesthesia Needles are single use, terminally sterilized devices available in various gauge/length combinations including the overall ranges of 18G – 29G and 30mm to 150mm. The proposed device shares technological characteristics with the predicate devices. The proposed device also has 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.

Summary of Technological Characteristics: (Continued)	The UNIEVER Disposable Spinal Anesthesia Needles share the same indications for use with both predicates. One difference exists in that the K112515 predicate includes indications for CSF sample collection while both the UNIEVER and the K110194 predicate do not include this additional indication. The UNIEVER Disposable Spinal Anesthesia Needles offer both Quincke and Pencil Point needle types as well as an introducer or guide needle [identical to both K112515 and K110194]. The UNIEVER Disposable Spinal Anesthesia Needles and the predicates are manufactured with materials commonly used in medical devices: stainless steel, polycarbonate, and polypropylene. Both the UNIEVER and the K110194 predicate identify the identical biocompatibility category, contact, and duration, and both reference testing for sensitization, irritation, and cytotoxicity. UNIEVER Disposable Spinal Anesthesia Needles as well as both predicates are sterilized using ethylene oxide (EO). UNIEVER Disposable Spinal Anesthesia Needles have a 5 year shelf life [identical to K112515]. Minor differences do exist between the UNIEVER Disposable Spinal Anesthesia Needles and the predicates. For example, the UNIEVER Disposable Spinal Anesthesia Needles offer a 29G needle while the two predicates have 25G [K110194] or 27G [K112515] as the smallest gauge offered. The UNIEVER Disposable Spinal Anesthesia Needles also differ in the minimum and maximum needle lengths offered with the UNIEVER needles ranging from 30mm – 150mm (28mm – 50mm for the introducer) with the predicates offering 25mm – 156mm (35mm for introducer) [K112515] and 90mm (38mm introducer) [K110194]. All the lengths offered for the UNIEVER Disposable Spinal Anesthesia Needles fall within the ranges offered by the identified predicates. Manufacturers offer different needle gauges and needle lengths based on the marketability of the device. This is common in the marketplace. 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 Anesthesia Needles including verification/validation testing to internal functional specifications which demonstrated that the device is safe and effective. Testing confirmed that the UNIEVER Disposable Spinal Anesthesia 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 (Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, and Pyrogenicity) and sterilization including additional endotoxin and particulate testing for CSF contact.
Conclusion:	*Unisis Corp* considers the *UNIEVER Disposable Spinal Anesthesia 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.