DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 1, 2016

IMEDICOM Co., Ltd.
c/o Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave. Ste 110
Fullerton CA 92831

Re: K150789
Trade/Device Name: SPINAUT-E, SPINAUT-I
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia conduction catheter
Regulatory Class: Class II
Product Code: BSO
Dated: January 21, 2016
Received: January 27, 2016

Dear Ms. Priscilla Chung:

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" (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 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,

Tejashri Purohit-Sheth, M.D.

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

Erin I. Keith, M.S.
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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)*
K150789

Device Name

SPINAUT-E, SPINAUT-I

Indications for Use *(Describe)*

SPINAUT-E is used for delivery of drugs that have been indicated for the epidural space.

SPINAUT-I is intended for the percutaneous introduction and placement of an epidural catheter.

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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510(k) Summary

(K150789)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Feb 17, 2016

1. **Applicant / Submitter**

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2. **Submission Correspondent**

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3. **Device**

- Trade Name: SPINAUT-E, SPINAUT-I
- Common Name: Anesthesia conduction catheter
- Classification Name: Anesthesia conduction catheter
- Product Code: BSO
- Classification regulation: 21 CFR 868.5120

4. **Predicate Device:**

- Primary Predicate Device: Myelotec Video Guided Catheter by Myelotec, Inc. (K980734)
- Reference Predicate Device: EBI TargetCath Fluoro-Guided Steerable Catheter System by EBI, L.P. (K032390)

5. Description:

SPINAUT-E consists of a flexible catheter, steering handle and a port for access to the lumen. The catheter has built in steering mechanism that allows for guiding the soft tip through the epidural space and soft tissues for optimal access to the source of distress. The port facilitates the connection of syringes to deliver therapeutic agents by physicians as appropriate to their diagnosis. It is supplied sterile and it is for single use.

There are 9 models in SPINAUT-E: E1000, E2000, E3000, E1100, E2100, E3100, S1000, S2000, and S3000. The catheter tip of the model E1000, E2000, and E3000 can be bent 50º to the left or to the right (the user can rotate the tip to adjust the direction), but the tip of the model E1100, E2100, and E 3100 can be bent either direction up to 100º. The S1000, S2000, and S3000 have an extra infusion port for drug so that the other main port can be used for other devices. Each model is characterized by the additional port, the lever, and the dimensions.

The SPINAUT-I is intended to be used to prepare or preserve a path for an epidural catheter. When placing SPINAUT-E into the patient, SPINAUT-I can be used as a replacement of the SPINUT-E Catheter Introducer Set. It is supplied sterile and it is for single use.

There are 3 models in SPINAUT-I: ID1000, ID2000, and ID3000 and each model is characterized by the length.

6. Indication for use:

SPINAUT-E is used for delivery of drugs that have been indicated for the epidural space.

SPINAUT-I is intended for the percutaneous introduction and placement of an epidural catheter.

7. Basis for Substantial Equivalence

SPINUAT-E and SPIANTU-I are substantially equivalent to the Myelotec Video Guided Catheter (K980734) made by Myelotec, Inc. and to the EBI TargetCath Fluoro-Guided Steerable Catheter System by EBI, L.P. (K032390).

There are no significant differences between the subject devices and the predicate devices that the subject devices have the similar intended use as the identified predicate devices and they are similar in fundamental scientific technology, design, and size, and they are sterilized via gamma irradiation.

The principles of operation are similar between the subject device and the predicate devices that they consist of a flexible catheter, steering handle and associated port for

access to the lumen. The port facilitates the connection of syringes to deliver physician selected therapeutic agents as appropriate to their diagnosis.

In terms of features, the major difference between the subject device and the primary predicate device is that the predicate device has one more designated port allowing the use of a flexible fiber optic endoscope. This is an extra feature that the predicate device offers but the common epidural catheters in the market are guided under fluoroscope as the subject device is, so we believe this difference would not render the device NSE. To support this, we have identified a reference predicate device which has the similar intended use and also used under fluoroscope as the subject device.

The materials used in the subject devices might be different from the predicate devices; however, the biocompatibility testing results of the subject device support that the subject devices are biocompatible. The size and the internal design also might be different between the devices but the performance testing results show that the subject device would perform as well as the predicate devices.

	Subject Device	**Primary Predicate Device**	**Reference Predicate Device**
Device Name	**SPINAUT-E** **SPINAUT-I**	**Myelotec Video Guided Catheter**	**EBI TargetCath Fluoro-Guided Steerable Catheter System**
510(k) Number	-	K980734	K032390
Product Code	BSO	BSO	BSO
Manufacturer	IMEDICOM Co., Ltd.	Myelotec, Inc.	EBI, L.P.
Intended Use	SPINAUT-E is used for delivery of drugs that have been indicated for the epidural space. SPINAUT-I is intended for the percutaneous introduction and placement of epidural catheters.	When used with a fiberoptic endoscope, this device can be used for observing epidural anatomy. pathology and delivery of drugs approved for epidural indications.	When used with a fluoroscope, the EBI® TargetCath™ Fluoro-Guided Steerable Catheter System can be used in the lumbar and sacral spine for delivery of drugs approved for epidural indications. The System may also be used for the purpose of assisting in the diagnosis and treatment of disease utilizing a caudal approach via the sacral hiatus.
Diameter(O.D.) of Catheter	1.7mm	2.7mm, 3.0mm, 3.3mm	2.4mm
Length of Catheter	300mm/ 315mm/ 330mm	300mm	280mm
Infusion port	One port	Dual port	Dual port
Material	SUS 304, PU, ABS, PE, PTFE, ABS, Polyurethane	-	-
Steering	Steerable	Steerable	Steerable
Single use	Yes	Yes	Yes

Components	Epidural catheter, guide wire, catheter introducer, introducer needle, and needle cap	Epidural catheter, guide wire, catheter introducer, introducer needle, and needle cap	Epidural catheter and various accessories
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Endoscope capable	Incapable	Capable	Incapable
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137-1, 2, 3 and ISO 11737-1, 2, 3, and the test results met the pre-set criteria.

- The tests to validate the shelf life of the device through the proposed shelf life were conducted using the accelerated aging method in accordance to ASTM F1980-07 and the test results validated 3 year shelf life. The following tests were conducted:
  - SPINAUT-E: Visual Inspection (Appearance), Size Measurement, Leakage Test (Catheter), Tensile strength (Catheter), Curved strength (Catheter), Fatigue test (Catheter), X-ray impermeable test, Corrosion resistance test, Flexural Rigidity (Catheter introducer and the needle), Pulling (Drawing) Test (Catheter introducer and the needle), Package Tensile Test, Package Peeling Test, Package Burst Test, Package Dye Penetration Test, Package Bubble Test, and Sterility Test.
  - SPINAUT-I: Visual Inspection (Appearance), Size Measurement, Leakage Test, Tensile strength, Flexural Rigidity, Connecting Part (Conical) Fitting, Package Tensile Test, Package Peeling Test, Package Burst Test, Package Dye Penetration Test, Package Bubble Test, and Sterility Test.

- The subject device falls into the category below based on the ISO 10993, Part I.
  Category: External communicating device (tissue/bone/dentin communicating), Limited exposure (<24 hours)
  The following biocompatibility tests were performed and the test results supported that the subject devices are biocompatible.
  - Extraction Test, Cytotoxicity (ISO 10993-5), Skin Sensitization (ISO 10993-10), Intracutaneous Reactivity (ISO 10993-10), Acute Systemic Toxicity Test (ISO 10993-11), Pyrogen (USP 37 <151>), Hoemolysis (ISO 10993-4), Endotoxin-specific LAL (Limulus Amebocyte Lysate) test (USP 38 NF33)

- Various bench tests and sterility test were performed to evaluate the performance and the safety of the subject devices and the test results met the pre-set criteria. The following tests have been conducted.
  - SPINUAT-E: Visual Inspection (Appearance), Leakage Test (Catheter), Tensile strength (Catheter), Curved strength (Catheter), Fatigue test (Catheter), X-ray impermeable test, Corrosion resistance test, Flexural Rigidity (Catheter introducer and the needle), Pulling (Drawing) Test (Catheter introducer and the needle), and Sterility Test.

- SPINAUT-I: Visual Inspection (Appearance), Leakage Test, Tensile strength, Flexural Rigidity, Connecting Part (Conical) Fitting, and Sterility Test.

The test results supported that the subject device is substantially equivalent to the predicate devices in safety and effectiveness.

9. Conclusion

Based on the similarities, we conclude that the SPINAUT-E and SPINAUT-I are substantially equivalent to the predicate devices.