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

March 16, 2016

IMEDICOM Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110
Fullerton, California 92831

Re: K151268
Trade/Device Name: SPINAUT-V, SPINAUT-S, SPINAUT-I
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 12, 2016
Received: February 22, 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" (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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K151268

Device Name

SPINAUT-V, SPINAUT-S, and SPINAUT-I

Indications for Use *(Describe)*

When used with a fiberoptic endoscope, SPINAUT-V can be used for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.

The SPINAUT-S is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease.

SPINAUT-I is intended for the percutaneous introduction and placement of a video guided catheter and/or an endoscope.

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
(K151268)

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

Date: Mar 15, 2016

1. **Applicant / Submitter**

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2. **Submission Correspondent**

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3. **Device**

- Trade Name: SPINAUT-V, SPINAUT-S, and SPINAUT-I
- Common Name: Arthroscope
- Classification Name: Arthroscope
- Product Code: HRX
- Classification regulation: Class II, 21 CFR 888.1100

4. **Predicate Device:**

- Myelotec Video Guided Catheter by Myelotec., Inc (K980734)

5. **Description:**

SPINAUT-V consists of a flexible catheter, steering handle and associated ports 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 design allows the use of a flexible fiber optic endoscope for visual examination of the area and surrounding tissues at the distal end of the catheter. This visual examination then allows the physician to diagnose the potential causes of neural distress and pain. SPINAUT-V is a sterile, single use device. When placing SPINAUT-V into the patient, SPINAUT-I can be used instead of SPINUT-V as an introducer device.

SPINAUT-S is a surgically invasive flexible fiberoptic system that can be used either with a video guided catheter (SPINAUT-V or other video guided catheters with proper catheter size) or with an introducer device such as SPINAUT-I. The SPINIUT-S is a reusable device that is supplied non-sterile with instructions for cleaning, sterilization and re-use. The SPINAUT-S can be used with the light source and camera system.

SPINAUT-I is intended to be used to prepare or preserve a path for a video guided catheter or an endoscope. It is supplied sterile and for single use.

6. Indication for use:

When used with a fiberoptic endoscope, SPINAUT-V can be used for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.

The SPINAUT-S is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease.

SPINAUT-I is intended for the percutaneous introduction and placement of a video guided catheter and/or an endoscope.

7. Basis for Substantial Equivalence

7.1. SPINAUT-V

SPINUAT-V is substantially equivalent to the Myelotec Video Guided Catheter (K980734) made by Myelotec, Inc.
There are no significant differences between the subject device and the predicate device. They share the following same characteristics.

- Intended Use
- Principle of Operation
- Design
- Size
- Sterilization Method

The materials used in the subject devices might be different from the predicate device (the materials of the predicate device are unknown.); however, the biocompatibility testing results of the subject device support that the subject devices are biocompatible

and the performance testing results show that the subject device would perform as well as the predicate device. Based on the test results, we conclude that despite the difference, the subject device is substantially equivalent to the predicate device.

	Subject Device	Predicate Device
Device Name	**SPINAUT-V**	**Myelotec Video Guided Catheter**
510(k) Number	K151268	K980734
Manufacturer	IMEDICOM Co., Ltd.	Myelotec., Inc.
Product Code	HRX	HRX
Intended Use	When used with a fiberoptic endoscope, SPINAUT-V can be used for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.	When used with a fiberoptic endoscope, this device can be used for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.
Diameter(O.D.) of Catheter	3.0mm	2.7 mm, 3.0mm, 3.3mm
Lengthof Catheter	300mm/ 315mm/ 330mm	300mm
Infusion port	Dual ports	Dual ports
Material	Sus 304, PU, ABS, PE, PTFE	-
Steering	Steerable	Steerable
Single use	Yes	Yes
Components	Video guided catheter, 15G needle, needle cap, introducer, guide wire	Video guided catheter, 15G needle, needle cap, introducer, guide wire
Biocompatibility	Biocompatible	Biocompatible
Endoscope capable	Capable	Capable
Insertion Point	Sacral Hiatus	Sacral Hiatus
Sterilization	Gamma Sterilization	Gamma Sterilization

7.2. SPINAUT-S

SPINUAT-V is substantially equivalent to the Myelotec Video Guided Catheter (K980734) made by Myelotec, Inc.
There are no significant differences between the subject device and the predicate device. They share the following same characteristics.

- Intended Use
- Principle of Operation
- Materials
- Design
- Sterilization Method

The field of view and the observation depth of the subject device are different from the predicate device; however, the performance testing results show that the subject device meets the specifications of those performance characteristics and also supports that it would perform as well as the predicate device. Based on the test results, we conclude that the subject device is substantially equivalent to the predicate device.

		Subject Device	**Predicate Device**
Trade name		**SPINAUT-S**	**Myelotec Video Guided Catheter**
510(k) Number		K151268	K980734
Manufacturer		IMEDICOM Co., Ltd.	Myelotec., Inc.
Product Code		HRX	HRX
Intended for use		The SPINAUT-S is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease.	When used with a fiberoptic endoscope, this device can be used for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.
Performance		Permits direct visualization of conditions inside the lower spine with minimal impact on the patient's musculoskeletal structure	Permits direct visualization of conditions inside the lower spine with minimal impact on the patient's musculoskeletal structure
Material	**Optical glass**	Inorganic glass	Inorganic glass
	Tube	Polyamide	Polyamide
	Inner path	Optical fiber	Optical fiber

Performance	**Field of view**	90°	60°
	Direct view	0°±10%	0°±10%
	Observation Depth	3 mm(f_1) ~ 20 mm(f_2)	5 mm(f_1) ~ 7.0 mm(f_2)
Size	**Total length**	950.5 mm	994.0 mm
Compatibility w/other devices		Video Guided Catheter Universal camera systems	Video Guided Catheter Universal camera systems
Chemical Safety		Biocompatible	Biocompatible
Sterilization		Non-sterilized	Non-sterilized

7.3. SPINAUT-I

SPINUAT-V is substantially equivalent to the Myelotec Video Guided Catheter (K980734) made by Myelotec, Inc.
There are no significant differences between the subject device and the predicate device. They share the following same characteristics.

- Intended Use
- Principle of Operation
- Design
- Materials
- Sterilization Method

We have found no significant differences between the two devices which would raise different questions of safety
and effectiveness.

	Subject Device	**Predicate Device**
Trade name	**SPINAUT-I**	**Myelotec Video Guided Catheter**
510(k) Number	K151268	K980734
Manufacturer	IMEDICOM Co., Ltd.	Myelotec., Inc.
Product Code	HRX	HRX

Intended for use		SPINAUT-I is intended for the percutaneous introduction and placement of Video Guided Catheter and/or Endoscope.	When used with a fiberoptic endoscope, this device can be used for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.
Performance		To be used to prepare or preserve a path for a lead.	To be used to prepare or preserve a path for a lead.
Material	**Body**	ABS	ABS
	Tube	Polyurethane	Polyurethane
Compatibility w/other devices		Video Guided Catheter Endoscope	Video Guided Catheter Endoscope
Chemical Safety		Biocompatible	Biocompatible
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 with ASTM F1980-07 and the test results validated 3 year shelf life.
- Biocompatibility tests were performed in accordance with ISO 10993-4, 5, 10, 11 and USP 37 <151>, and the test results supported that the subject devices are biocompatible.
- The following bench tests were performed to evaluate the performance and the safety of the subject devices and the test results met the pre-set criteria.

SPINAUT-V

No.	Test	Test Description
1	Appearance	Visual Inspection
2	Leakage Test (Catheter)	Evaluate if the catheter leaks any water using a pressure gauge
3	Tensile strength (Catheter)	Test in accordance with ISO 10555-1, Intravascular Catheters – sterile and single use catheter – Part 1: General requirements.
4	Curved strength (Catheter)	Measure a carved angle of the catheter.

5	Fatigue test (Catheter)	Evaluate the fatigue strength of the catheter
6	X-ray impermeable test	Evaluate if the device can be shown on an X-ray image clearly.
7	Corrosion resistance test	Test in accordance with ISO 10555-1 Intravascular Catheters – sterile and single use catheter – Part 1: General requirements.
8	Flexural Rigidity (Catheter introducer)	Test in accordance with MFDS Notification No. 2013-214: Standard Specifications for Medical Device – Sterile hypodermic needles for single use - Clause 5.
9	Sterility test	Test in accordance with Korean Pharmacopeia (10th Edition) : General Requirements for Tests and Assays / Sterility Test

SPINAUT-S

No.	Test	Test Description
1	Direction of View	Test in accordance with ISO 8600-3
2	Field of View	Test in accordance with ISO 8600-3:2013
3	(Depth of Focus) Observation Depth	Test in accordance with ISO 8600-1:2005 and ISO 12233:2014
4	Internal Pressure (Capacity to Resist Pressure)	Test in accordance with ISO 8600-1:2005
5	Dimensions	Measure the total length, insertion portion and the outer diameter by vernier calipers.

SPINAUT-I

No.	Test	Test Description
1	Appearance	Visual Inspection
2	Leakage Test	Evaluate if the catheter leaks any water using a pressure gauge
3	Tensile strength	Measure tensile strength of the device
4	Flexural Rigidity	Test in accordance with MFDS Notification No. 2013-214: Standard Specifications for Medical Device – Sterile hypodermic needles for single use - Clause 5.
5	Connecting Part (Conical) Fitting	Test in accordance with ISO 594-1 and ISO 594:2. ▪ Gauging test ▪ Liquid leakage ▪ Air leakage ▪ Separation force ▪ Unscrewing torque ▪ Ease of assembly

		▪ Resistance to overriding ▪ Stress cracking
6	Sterility test	Test in accordance with Korean Pharmacopeia (10th Edition) : General Requirements for Tests and Assays / Sterility Test

The test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

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