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 18, 2016

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

Re: K150915
Trade/Device Name: SPINAUT-P
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessoriesv
Regulatory Class: Class II
Product Code: GEI
Dated: February 24, 2016
Received: February 26, 2016

Dear Ms. 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,

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)*
K150915

Device Name

SPINAUT-P

Indications for Use *(Describe)*

The SPINUAT-P is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

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

(K150915)

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

Date: Mar 17, 2016

1. **Applicant / Submitter**

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2. **Submission Correspondent**

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3. **Device**

- Trade Name: SPINAUT-P
- Common Name: Electrosurgical accessory
- Classification Name: Electrosurgical cutting and coagulation device and accessories
- Product Code: GEI
- Classification regulation: 21 CFR 878.4400

4. **Predicate Device:**

- ArthroCare® Coblator IQ™ Perc-D®, SpineWand® (Coblator IQ DLR and DLG SpineWands) by Arthrocare Corp. (K132099)
- L'DISQ by U&I Corporation (K132797)

5. **Description:**

The SPINAUT-P is a minimally invasive RF electrode device offered in 496mm length for percutaneous disc decompression surgery using radiofrequency energy and designed

for use with radiofrequency generators in RF procedure. SPINAUT-P is intended to be placed into the epidural space or posterolateral / posterocentral area in the disc to remove, ablate or coagulate disc material in the area. The electrode consists of two stainless steel shafts with straight electrode configuration design. The shaft is housed in a coating composed of Polyamide. The device is single-use gamma radiation sterilized and is compatible with most standard electrosurgical generators that provide a cable with two pin outlet (2-pin, 22mm) with 1kVp maximum electrical capacity.

6. Indication for use:

The SPINUAT-P is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

7. Basis for Substantial Equivalence

The subject device is the same as the predicate device in the indications for use, materials, energy source, performance specifications, electrode thickness, mode of operation (bipolar) and sterilization method. The major difference is the electrode length but this difference does not raise a question of safety and performance since the electrode is coated with the polyamid to protect the patient and the user from electrical leakage and burn. In this regard, the longer electrode does not raise a question of safety issue. The electrode length would not be a performance affecting factor either since the thickness of the tip would matter the most which is the only part exposed to the patient. The performance test results submitted in this 510K submission also supports that the subject device is substantially equivalent to the predicate devices despite this difference.

Trade name	**SPINAUT-P**	**ArthroCare® Coblator IQ™ Perc-D® SpineWand® (Coblator IQ DLR and DLG SpineWands)**	**L'DISQ**
Manufacture	IMEDICOM Co., Ltd.	Arthrocare Corp.	U&I Corporation
510(k) number	-	K132099	K132797
Product Code	GEI	GEI	GEI

Indications for Use		The SPINUAT-P is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.	The ArthroCare Coblator IQ Perc-D Spine Wands (Coblator IQ DLR and Coblator IQ DLG SpineWands) are indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated lumbar and lumbosacral discs. The Wands are designed to be used exclusively with the ArthroCarc Coblator IQ Controller.	The L'DISQ is indicated for coagulation and ablation of disc material to treat symptomatic patients with contained herniated discs.
Principle of Operation		Electrode is activated using the generator which starts the coblation process to ablate disc tissue. The coblation process involves use of a conductive media to create a plasma layer to ablate tissue.	Electrode is activated using the generator which starts the coblation process to ablate disc tissue. The coblation process involves use of a conductive media to create a plasma layer to ablate tissue.	Electrode is activated using the generator which starts the coblation process to ablate disc tissue. The coblation process involves use of a conductive media to create a plasma layer to ablate tissue.
Material	**Electrode**	Stainless Steel 304	Stainless Steel 304	Stainless Steel 304
	Handle	Polyamide	Polyamide	Polyamide
Perfor - mance	**RF leakage current**	≤7.2 dfL mA	≤7.2dfL mA	≤7.2dfL mA
Size	**Electrode length**	496.0 mm	300.0~350.0mm	210.0mm
	Electrode thickness	1.0 mm	0.8~1.0mm	0.7mm 1.0mm
Compatibility w/other devices		Standard RF generator	with the ArthroCare Coblator IQ Controller	Standard RF Generator
Chemical Safety		Biocompatible	Biocompatible	Biocompatible

Sterilization	Gamma sterilized	Gamma sterilized	Gamma sterilized

* dfL
d : the cable's smallest external dimension(unit : mm)
f : test frequency(unit : MHz)
L : length of cable submerged in saline solution

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.

No.	Test	Test Description / Referenced Standard
1	Appearance	Visual Inspection
2	Electrical Conductivity Test	Connect an electric circuit meter to the device and check electrical conductivity by electric circuit tester.
3	Tensile Strength Test of Electrode Cord	Test in accordance with ANSI/AAMI HF18:2001 Electrosurgical devices Clause 4.2.5.5
4	Package Tensile Test	Test in accordance with ASTM D882-12, standard test methods for tensile properties of thin plastic sheeting. (Ophthalmic)
5	Package Peeling Test	Test in accordance with ASTM F88/F88M-09, standard test method for seal strength of flexible barrier materials. (Sterility)
6	Package Dye Penetration Test	Test in accordance with ASTM F1929-12, standard test method for detecting seal leaks in porous medical packaging by dye penetration. (Sterility)
7	Sterility Test	Test in accordance with ISO 11737-2 Second edition 2009-11-15, sterilization of medical devices - microbiological methods - part 2: tests of sterility performed in the definition, validation and maintenance of a sterilization process. (Sterility)

- The following 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 device is biocompatible.

No.	Test	Test Description / Referenced Standards
1	Extraction Test	-
2	Cytotoxicity	ISO 10993-5:2009/(R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity. (Biocompatibility)
3	Skin Sensitization	ISO 10993-10 Third Edition 2010-08-01, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization. (Biocompatibility)
4	Intracutaneous reactivity	ISO 10993-10 Third Edition 2010-08-01, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization. (Biocompatibility)
5	Acute Systemic Toxicity Test	ISO 10993-11 Second edition 2006-08-15, biological evaluation of medical devices part 11: tests for systemic toxicity. (Biocompatibility)
6	Pyrogen	USP 37-NF32:2014, <151> pyrogen test (usp rabbit test). (Sterility)
7	Hoemolysis	ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

- The following electrical safety and bench tests were performed to evaluate the performance and the safety of the subject device and the test results met the pre-set criteria.

No.	Test	Test Description / Referenced Standards
1	Electrical Conductivity Test	Evaluate if the electrode is able to pass electricity.
2	Cable Dielectric Strength Test	IEC 60601-2-2 Edition 5.0 2009-02, medical electrical equipment - part 2-2: particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories [including: technical corrigendum 1 (2014)]. (General Plastic Surgery/General Hospital)

		• Clause 201.8.8.3.104 Line voltage withstanding capability • Clause 201.8.8.3.103 High frequency voltage withstanding capability
3	High Frequency Leakage Test of Electrode	Test in accordance with ANSI/AAMI HF 18:2001 *Electrosurgical Devices* • Clause 4.2.5.2
4	Appearance	Visual Inspection
5	Size Measurement	Measure the size of the test article by vernier calipers.
6	Tensile Strength Test of Electrode Cord	Test in accordance with ANSI/AAMI HF 18:2001 *Electrosurgical Devices* • Clause 4.2.5.5
7	Sterility test	Korean Pharmacopeia (10th Edition) : General Requirements for Tests and Assays / Sterility Test

- We compared the tissue removal, durability, and ability to navigation in the lesion (performance to be introduced, directed to and extracted from the target lesion) of our RF Electrode SPINAUT-P and the predicate device, L'disQby U and I (K132797) using porcine spines. The test results demonstrated the device being as safe and as effective as the predicate device.

No.	Test	Test Description
1	Performance Comparison Test with the predicate device using porcine spines	• Tissue Removal Performance • Durability of Electrode • Ability to be introduced, directed to and extracted from the surgical site(target area)

All 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-P is substantially equivalent to the predicate devices.