JUL 3 0 2014

U&I CORPORATION

5. 510(k) Summary

Manufacturer: U & I Corporation
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si
Gyeonggi-do, 480-859, Korea
Gyeong-Je Kwon, Regulatory Affairs Specialist

Sponsor: U & I Corporation
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si
Gyeonggi-do, 480-859, Korea

Sponsor Contact: Gyeong-Je Kwon, Regulatory Affairs Specialist

Date Prepared: February 21, 2014

Device Name: Trade Name: L'DISQ®

Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (GEI), per 21 CFR 878.4400

Product Code: GEI

Predicate Devices: ArthroCare® Perc™DC/DLR SpineWand™
(K010811, K030954, K053447, K061259)

Description of Device:

The L'DISQ® is a plasma electrode which is 1.0 mm(PD01, PD02, PD03, PD04, PD05, PD07 and PC01) or 0.7 mm(PC02) thickness based on the high frequency electrosurgical system. L'DISQ® removes the disc lesions that are causing pain by a plasma based radiofrequency device.

L'DISQ® is a single use device and there are 3-type of designs (L'DISQ, L'DISQ C, L'DISQ C.7) according to the level of spine treated. When using the L'DISQ®, the users should also study carefully "Operation Manual" of the electrosurgical power generator as well as "Instructions for Use" and "Procedure Technique" of L'DISQ®.

1. L'DISQ (PD01, PD02, PD03, PD04, PD5, PD07): Device for lumbar disc
 - L'DISQ consists of seven components:
  (1) BIPOLAR TIP 1.0MM (CAP + INSULATOR + RING + POLYMER TUBE + WIRE 0.2mm + COPPER WIRE)
  (2) TIP SUPPORT (25mm, 45mm, 15mm, 9mm, 35mm)
  (3) TIP PROTECTION
  (4) POLYIMIDE TUBE
  (5) RF CONNECTOR (4PIN)
  (6) MANIPULATOR
  (7) SPRING STOPPER

2. L'DISQ C (PC01): Device for cervical disc
 - L'DISQ C consists of six components:
  (1) L'DISQ C BIPOLAR TIP (CAP + INSULATOR + RING + POLYMER TUBE-C + WIRE 0.2mm + COPPER WIRE)
  (2) TIP SUPPORT-C 17mm
  (3) POLYIMIDE TUBE
  (4) L'DISQ C MANIPULATOR
  (5) SPRING STOPPER
  (6) MANIPULATOR CABLE

3. L'DISQ C.7 (PC02): Device for cervical disc
 - L'DISQ C.7 consists of four components:
  (1) L'DISQ C.7 BIPOLAR TIP (CAP+INSULATOR+EDM WIRE)
  (2) TIP SUPPORT
  (3) L'DISQ C.7 MANIPULATOR
  (4) MANIPULATOR CABLE

Intended Use:
The L'DISQ® is indicated for coagulation and ablation of disc material to treat symptomatic patients with contained herniated discs.

Substantial Equivalence:
In establishing substantial equivalence to the predicate device, L'DISQ® evaluated the indication for use, components, performance, approaching method, energy source, and sterilization methods of those systems.

1. Performance Testing
To evaluate the performance of L'DISQ®, we conducted following tests.

(1) Removal test for nucleus pulposus
(2) Durability test for electrode

The test result met all acceptance criteria and verifies that performance of the L'DISQ® is substantially equivalent to the predicate device, Perc™DC/DLR SpineWand™ (ArthroCare).

2. Conclusion
The data and information provided in this submission support the conclusion that the L'DISQ® is substantially equivalent to its predicate device with respect to indications for use, components, performance, approaching method, energy source and sterilization method and other technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2014

U & I Corporation
Gyeong-Je Kwon
Regulatory Affairs Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijungbu-si, Gyeonggi-do 480-059
Korea

Re: K132797
Trade/Device Name: L'DISQ®
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 20, 2014
Received: June 23, 2014

Dear Kwon:

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,

David Krause -S

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)*
K132797

Device Name

L'DISQ®

Indications for Use *(Describe)*

The L'DISQ® is indicated for coagulation and ablation 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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