



Food and Drug Administration
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August 26, 2016

LCCS Products Limited
% Mr. Field Fu
Shenzhen Joyantech Consulting Co., Ltd.
No. 55 Shizhou Middle Road, Nanshan District
Shenzhen, Guangdong GD755
China

Re: K152642

Trade/Device Name: LCCS Radiofrequency (RF) Electrode
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: August 9, 2016
Received: August 22, 2016

Dear Mr. Fu:

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,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152642

Device Name

LCCS Radiofrequency (RF) Electrode

Indications for Use (Describe)

LCCS Radiofrequency (RF) Electrode is indicated for use in temperature-controlled RF heat lesion procedures of peripheral nerve tissue for the relief of pain.

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

1. Contact Details

1.1 Applicant information

| | |
|--------------------------------|---|
| Applicant Name | LCCS Products Limited |
| Address | Flat A, 9/F., Hennessy Plaza, 164-166 Hennessy Road, Wanchai, Hong Kong |
| Phone No. | +852-82321050 |
| Fax No. | +852-35430978 |
| Contact person | Ming Lin |
| Contact person's e-mail | minglin2006@yahoo.com.cn |
| Company e-mail | lccsmed@126.com |
| Date Prepared | July 8, 2016 |
| Website | www.lccsmed.com |

1.2 Consultant information

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|---|---|
|  卓远天成 | Name Shenzhen Joyantech Consulting Co., Ltd |
| Address | Room 2032, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen |
| Phone No. | +86-755-86069197 |
| Contact person | Field Fu |
| Contact person's e-mail | cefda13485@163.com |
| Website | http://www.cefda.com |

2. Device information

| | |
|----------------------------|--|
| Trade name | LCCS Radiofrequency (RF) Electrode |
| Common name | Radiofrequency Electrode |
| Model | RE-D (D for Disposable), RE-R (R for Reusable) |
| Classification | II |
| Classification name | Probe, Radiofrequency Lesion |
| Product code | GXI |
| Regulation No. | 882.4725 |

3. Legally Marketed Predicate Device

| | |
|----------------------|----------------------------------|
| Trade Name | OWL Sterile Single Use RF Probes |
| 510(k) Number | K110593 |
| Product Code | GXI |
| Manufacturer | Diros Technology Inc. |

| | |
|----------------------|------------------------|
| Trade Name | OWL Reusable RF Probes |
| 510(k) Number | K010202 |
| Product Code | GXI |
| Manufacturer | Diros Technology Inc. |

4. Device Description

LCCS Radiofrequency (RF) Electrode is used in conjunction with RF Generator to create RF lesions of nerve tissue or for use in percutaneous nerve blocks. The RF Electrode connector side connects with RF Generator and thermocouple side which fits in with RF Cannula. The RF generator applies temperature-controlled RF energy into targeted nerve tissue via an RF Electrode to create a heat lesioning of peripheral nerve tissue.

LCCS RF Electrode includes LCCS Disposable RF Electrode and LCCS Reusable RF Electrode. LCCS Disposable RF Electrode Part No. includes RE2750-D-LC, RE27100-D-LC, RE27150-D-LC, and RE27200-D-LC.

LCCS Reusable RF Electrode Part No. includes RE2750-R-LC, RE27100-R-LC, RE27150-R-LC, RE27200-R-LC, RE2550-R-LC, RE25100-R-LC, RE25150-R-LC, and RE25200-R-LC.

5. Intended Use

LCCS Radiofrequency (RF) Electrode is indicated for use in temperature-controlled RF heat lesion procedures of peripheral nerve tissue for the relief of pain.

6. Indication for Use

LCCS Radiofrequency (RF) Electrode is indicated for use in temperature-controlled RF heat lesion procedures of peripheral nerve tissue for the relief of pain.

7. Substantial Equivalence Comparison

7.1 Comparison between LCCS Disposable RF Electrode and OWL Sterile Single Use RF Probes

| Characteristic | LCCS Disposable RF Electrode | OWL Sterile Single Use RF Probes (K110593) | Comments |
|-----------------------|---|--|-----------------|
| Intended Use | LCCS Radiofrequency (RF) Electrode is indicated for use in temperature-controlled RF lesion procedures of peripheral nerve tissue for the relief of pain. | The OWL Sterile Single use R.F. Probe/Temperature Sensor is intended for use in Radio-Frequency Heat Lesion procedures for relief of pain. | Equivalent |

| Characteristic | | LCCS Disposable RF Electrode | OWL Sterile Single Use RF Probes (K110593) | Comments |
|---|--------------------------------|--|--|---|
| Diameter | | 0.4mm (27gauge) | 25 AWG (25gauge) 27 AWG (27gauge) | Equivalent |
| Lengths Available (Cannulae length to be used with) | | 69mm (5cm) 117mm (10cm) 160mm (15cm) 220mm (20cm) | 65.8mm (5cm) 116.5mm (10cm) 161mm (15cm) 194mm (20cm) | Equivalent |
| Temperature Measurement Capabilities | Temperature measurement device | Thermocouple | Thermistor Thermocouple | Temperature accuracy of thermocouple has been demonstrated through comparison testing with predicate. The LCCS Disposable RF Electrode device is as accurate as the predicate device. |
| | Range | 40~100 °C | Unknown | |
| | Tolerance | ±5% | Unknown | |
| Single Use | | Yes | Yes | Same |

7.2 Comparison between LCCS Reusable RF Electrode and OWL Reusable RF Probes and Cannulae

| Characteristic | LCCS Reusable RF Electrode | OWL Reusable RF Probes (K010202) | Comments |
|----------------|---|---|------------|
| Intended Use | LCCS Radiofrequency (RF) Electrode is indicated for use in temperature-controlled RF lesion procedures of peripheral nerve tissue for the relief of pain. | The OWL R.F. Probe/Temperature Sensor is intended for use in Radio-Frequency Heat Lesion procedures for relief of pain. | Equivalent |
| Material | Electrode tube: 304 Stainless Steel Tube | Electrode tube: 304 Stainless Steel Tube | Same |

| Characteristic | | LCCS Reusable RF Electrode | OWL Reusable RF Probes (K010202) | Comments |
|--|--------------------------------|--|---|---|
| Diameter | | 0.4mm (27gauge) 0.5mm (25gauge) | 25 gauge (0.5mm OD) | Although the diameter of the predicate OWL Reusable RF Probes do not contain 27gauge, but the OWL Sterile Single Use RF Probes (K110593) contain the diameter of 27gauge, the difference between the predicate OWL Reusable RF Probes and the OWL Sterile Single Use RF Probes (K110593) is just for single use or not. Also, diameter of probe is determined by diameter of cannula. So the difference of electrode's diameter does not change the intended use of the device and does not introduce any new issues of safety and effectiveness. |
| Lengths Available (Cannulae length to be used with) | | 69mm (5cm) 117mm (10cm) 160mm (15cm) 220mm (20cm) | 65.8mm (5cm) 116.5mm (10cm) 161mm (15cm) | Although the cannulae length to be used with of the predicate OWL Reusable RF Probes do not contain 200mm, but the OWL Sterile Single Use RF Probes (K110593) contain the length of 200mm, the difference between the predicate OWL Reusable RF Probes and the OWL Sterile Single Use RF Probes (K110593) is just for single use or not. Also, length of probe is determined by length of cannula. So the difference of length does not change the intended use of the device and does not introduce any new issues of safety and effectiveness. |
| Temperature Measurement | Temperature measurement device | Thermocouple | Thermistor Thermocouple | Temperature accuracy of thermocouple has been demonstrated through comparison testing with |
| | Range | 40~100 °C | Unknown | |

| Characteristic | | LCCS Reusable RF Electrode | OWL Reusable RF Probes (K010202) | Comments |
|----------------|-----------|----------------------------|----------------------------------|--|
| Capabilities | Tolerance | ±5% | Unknown | predicate. The LCCS Reusable RF Electrode device is as accurate as the predicate device. |
| Single Use | | No | No | Same |

8. Non-clinical Testing

All nonclinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing are demonstrating the compliance to the standards and matching the performance of new devices to the predicate devices.

The following performance data were provided in support of the substantial equivalence determination.

8.1 LCCS Disposable RF Electrode nonclinical testing list

| Test | Test Method Summary | Results | |
|-------------------------------|--|--|--------|
| Dimension | Measured the electrode nominal OD and effective length. | Passed | |
| Cleanness | Observed the surface cleanness under normal or corrected vision with 300LX to 700LC illumination. | Passed | |
| Appearance | Inspect the appearance under normal or corrected vision with 300LX to 700LC illumination. | Passed | |
| Corrosion resistance | ISO 13402 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure | Passed | |
| Temperature accuracy | Verified the accuracy by performance testing. | Passed | |
| Degree of connection rigidity | Verified the connection rigidity by static tensile test. | Passed | |
| Biocompatibility | Cytotoxicity | ISO 10993-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity | Passed |
| | Sensitization | ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization | Passed |
| | Irritation | ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization | Passed |
| | EtO and ECH | ISO 10993-7 Biological evaluation of medical devices –Part 7:Ethylene oxide sterilization | Passed |

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|--|---------------|--|--------|
| | residuals | residuals | |
| | Sterilization | ISO 11135 ISO 11135 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices | Passed |
| | EMC | IEC 60601-2-2 Medical electrical equipment Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories | Passed |

8.2 LCCS Resuable RF Electrode nonclinical testing list

| Test | | Test Method Summary | Results |
|------------------|-------------------------------|--|---------|
| | Dimension | Measured the electrode nominal OD and effective length. | Passed |
| | Cleanness | Observed the surface cleanness under normal or corrected vision with 300LX to 700LC illumination. | Passed |
| | Appearance | Inspect the appearance under normal or corrected vision with 300LX to 700LC illumination. | Passed |
| | Corrosion resistance | ISO 13402 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure | Passed |
| | Temperature accuracy | Verified the accuracy by performance testing. | Passed |
| | Degree of connection rigidity | Verified the connection rigidity by static tensile test. | Passed |
| Biocompatibility | Cytotoxicity | ISO 10993-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity | Passed |
| | Sensitization | ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization | Passed |
| | Irritation | ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization | Passed |
| | Sterilization | ISO 17665-1 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices | Passed |
| | EMC | IEC 60601-2-2 Medical electrical equipment | Passed |

| | | |
|--|---|--|
| | Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories | |
|--|---|--|

9. Clinical Testing

Substantial equivalence does not depend on the clinical test data.

10. Conclusions

The non-clinical data demonstrate that the LCCS RF Disposable and Reusable Electrode devices perform comparably to the predicate devices that are currently marketed for the same intended use.