February 5, 2020

Auckland Medical Polymer (Tianjin) Co., Ltd.
Bei Lei Gao
Chief Financial Officer
Building D5-2, XEDA International Industrial Park
Xiqing Economic Development Area
Tianjin, China 300385

Re: K183148
Trade/Device Name: OKLand Patient Return Electrode Pad
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 31, 2019
Received: January 2, 2020

Dear Bei Lei Gao:

This letter corrects our substantially equivalent letter of February 4, 2020.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183148

Device Name
OKLand Patient Return Electrode Pad

Indications for Use *(Describe)*
OKLand Patient Return Electrode Pad is designed to be used whenever monopolar electrosurgery is indicated. The intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units (ESU) or generators in monopolar surgery.

This device is restricted to use with isolated monopolar electrosurgical generators, not intended for radio frequency ablation.

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.

OKLand Patient Return Electrode Pad

510 (k) Summary

A. Date Prepared: Nov. 29, 2018

B. Submitter and Owner

Auckland Medical Polymer (Tianjin) Co., Ltd.
Building D5-2, XEDA International Industrial Park, Xiqing Economic Development Area (XEDA), Tianjin, 300385, China
Official Correspondent: Bei Lei Gao
Tel: 0086-15122456760
E-mail: oklmedical@163.com
jessiegao@okltj.com
Submission Contact: Bei Lei Gao
Tel: 0086-15122456760
Email: oklmedical@163.com
jessiegao@okltj.com

Establishment Registration Number: 3011559089

C. Proposed Device

Propriety Name: OKLand Patient Return Electrode Pad
Common Name: Patient Return Electrode
Classification Name: Electrosurgical, cutting & Coagulation & Accessories
Classification regulation: 21 CFR 878. 4400
Class: II
Product Code: GEI

D. Predicate and Reference Devices

Predicate Device: MegaSoft Universal Patient Return Electrode (K133726)
Reference device: Mega 2000 Soft Patient Return Electrode Pad (K021077)
Reference Device: Mega 2000 Soft Dual Cord Patient Return Electrode Pad (K031285)
Reference Device: Mega Soft Patient Return Electrode (K080741)

E. Device Description

The device consists of a layer of conductive Copper-Nickel fibbers-coated polyester mesh, encased in a viscoelastic and dielectric polyurethane (PU) gel. These two materials are wrapped and sealed with PU membrane. A (or two) BVR lead (s) is attached outside of the pad, one side of the lead is connected to the conductive mesh, and the other side of the lead is assembled with different kinds of connectors.

This device should be operated by qualified healthcare personnel and is intended to be used for patients with a body weight no less than 0.35 kg (0.8lb). , with no upper body weight limit.

The Okland Patient Return Electrode Pad is slightly different with the predicate device Mega 2000 Soft Patient Return Electrode Pad in the following technology features: physical size, capacitance, effective contacting area, and body contacting materials. However, test results verified the differences do not raise additional safety or effectiveness concerns.

F. Indications for Use

OKLand Patient Return Electrode Pad is designed to be used whenever monopolar electrosurgery is indicated. The intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units (ESU) or generators in monopolar surgery.

This device is restricted to use with isolated monopolar electrosurgical generators, not intended for radio frequency ablation.

G. Technological Characteristic Comparison

The Propose device is found to possess similar technological characteristics under the premises of sharing same intended use after comparing materials, physical specifications and other aspects, the detailed information is listed in Substantial Equivalence Comparison.

H. Performance Data

Biocompatibility

Biocompatibility evaluation and testing were performed to demonstrate that the patient-contacting portions of the subject device meet all applicable safety requirements related to

material toxicity and biological responsiveness of limited contacting devices. The results demonstrated that these components met the requirements of ISO 10993-1 with regard to Cytotoxicity, Sensitization, Irritation Response.

Electrical safety and compatibility

The subject device fulfills all applicable requirements to demonstrate that the device is compliant with the current electrical safety standards:

ES60601-1:2005/(R) 2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2-2014, 2014 MEDICAL ELECTRICAL EQUIPMENT – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-2-2:2017, 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.

Bench Performance Test

Performance testing was conducted as recommended by the FDA guidance Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery to support substantial equivalence to the predicate device. The results demonstrated the subject device can perform the intended use as safe and effective as the predicate device. The technological differences between the subject device and the predicate device did not raise any different questions of safety or effectiveness.

Clinical Studies

No clinical data is presented in this submission

I. Conclusion

Based on the technological characteristics and non-clinical performance data, OKLand Patient Return Electrode Pad is as safe and effective as the predicate device due to same intended use and similar technical characteristics.