March 7, 2018

Lameditech Co., Ltd.
% Ken Pilgrim
Senior Consultant, RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K172818
Trade/Device Name: LMT-3000
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 31, 2018
Received: February 6, 2018

Dear Ken Pilgrim:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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)*

K172818

Device Name
LMT-3000

Indications for Use *(Describe)*
The LMT-3000 is a portable, battery-operated laser lancing device indicated for obtaining capillary blood samples in both institutional and at-home settings.

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

LMT-3000

K172818

1. Submission Sponsor

Lameditech Co., Ltd.

#1002, ACE High End Tower 6th

234, Beotkkot-ro, Geumcheon-gu, Seoul

The Republic of Korea

Contact: Jong Seuk Choi

Title: CEO

2. Submission Correspondent

Emergo Global Consulting, LLC

2500 Bee Cave Road

Building 1, Suite 300

Austin, TX 78746 USA

Office Phone: (512) 327.9997

Contact: Ken Pilgrim

Title: Senior RA/QA Consultant

3. Date Prepared

October 2, 2017

4. Device Identification

Trade/Proprietary Name:	LMT-3000
Common/Usual Name:	Laser Lancing Device
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR § 878.4810

Product Code: GEX, Powered Laser Surgical Instrument

Device Class: Class II

Classification Panel: General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

K013021 Innotech USA, Inc. LightLance™ Laser Skin Perforator

6. Indication for Use Statement

The LMT-3000 is a portable, battery-operated laser lancing device indicated for obtaining capillary blood samples.

7. Device Description

The LMT-3000 lancing device uses a battery-powered laser beam (Er:YAG laser technology), which makes a tiny hole in the skin to obtain a capillary blood sample. The LMT-3000 ablates the epidermis and a thin layer of papillary dermis with minimal photothermal and photomechanical damage to the surrounding tissue.

8. Substantial Equivalence Discussion

The following table compares the LMT-3000 to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-A – Comparison of Characteristics

Manufacturer	**Lameditech Co., Ltd.**	**Innotech USA, Inc.**
Trade Name	**LMT-3000**	**LightLance Laser Perforator**
510(k) Number	K172818	K013021
Product Code	GEX	GEX
Regulation Number	21 CFR § 878.4810	21 CFR § 878.4810
Regulation Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument
Indications for Use	The LMT-3000 is a portable, battery-operated laser lancing device indicated for obtaining capillary blood samples.	The LightLance™ Laser Skin Perforator is intended to be used for ablation of skin tissue to establish capillary blood access. The LightLance™ Laser Skin Perforator general indication for use is for the perforation of skin to draw capillary blood for screening purpose. The device is specifically indicated for

Manufacturer	Lameditech Co., Ltd.	Innotech USA, Inc.
Trade Name	**LMT-3000**	**LightLance Laser Perforator**
		obtaining capillary blood samples for subsequent analysis of blood glucose concentration in both institutional and home settings
Mechanism of Action	The LMT-3000 Laser Skin Perforator is a pulsed erbium doped yttrium-aluminum-garnet(Er:YAG) laser. It outputs a single pulse of laser light with a wavelength of 2940 nm, which ablates a small hole in the skin to a depth sufficient to access capillary blood.	The LightLance Laser Skin Perforator is a pulsed erbium doped yttrium-aluminum-garnet (Er:YAG) laser. It outputs a single pulse of laser light with a wavelength of 2940 nm, which ablates a small hole in the skin to a depth sufficient to access capillary blood.
Technology Overview	The wavelength of this laser is 2.94 μm, which matches water's absorption peak. Taking in to account that the water is the major constituent of organic tissue, it's possible to explain the strong absorption of tissue for this wavelength. On the other hand, due this strong absorption in water, this laser exhibits a little penetration depth	The wavelength of this laser is 2.94 μm, which matches water's absorption peak. Taking in to account that the water is the major constituent of organic tissue, it's possible to explain the strong absorption of tissue for this wavelength. On the other hand, due this strong absorption in water, this laser exhibits a little penetration depth
Anatomical Location	Fingertip	Fingertip
Conditions of Use	1. Set the Power Level 2. Position the Fingertip 3. Press the Discharge button. 4. Collect the Blood Sample	1. Set the Power Level 2. Position the Fingertip 3. Press the Discharge button. 4. Collect the Blood Sample
Material	Polycarbonate	Unknown
Battery Operated	Rechargeable battery (3.7 Vdc)	Yes
Power Supply	100~240Vac, 50-60 Hz	Not known
Output	5 Vdc, 1.0 A	Not known
Applied Parts	BF Type	Not known
Laser Source	Er:YAG	Er:YAG
Laser Class	Class 4 (IEC 60825-1)	Class 4 (IEC 60825-1)

Manufacturer	Lameditech Co., Ltd.	Innotech USA, Inc.
Trade Name	**LMT-3000**	**LightLance Laser Perforator**
Laser Pulse Repetition Rate	Single	Single
Laser wavelength spectrum	2940 nm ± 10%	2940 nm ± 10%
Degree of protection against ingress of water or particulate matter	IP22	Not known
Unit Dimensions	34.9 (W) X 102.45 (D) X 132.2 mm (H)	Not known
Weight	170 g	Not known
Operating Temperature	Ambient temperature +5 to +40°C	Not known
Operating Humidity	Relative humidity 5 to 90%, noncondensing	Not known
Storage Temperature	Ambient temperature -10 to +60°C	Not known
Storage Humidity	Relative humidity 5 to 90%, noncondensing	Not known
Single-Use	No	No
Battery Type	3.7 Li-Polymer Battery 700 mAh, rechargeable, replaceable (Type ICR-18350)	Not known
Sterile	No	No
Complies with ISO 10993-1	Yes	Yes
Electrical Safety Testing Passed	Testing passed	Testing passed
Conditions of Use	Rx Only	Rx Only

5. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of LMT-3000 and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Lameditech Co., Ltd. completed a number of non-clinical performance tests. The LMT-3000 meets all the requirements for overall design,

biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The LMT-3000 passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support the safety and efficacy of the subject device.

- Biocompatibility testing per ISO 10993-1
- Electrical safety testing per IEC 60601-1
- Electromagnetic Compatibility (EMC) testing per IEC 60601-1-2
- Laser Safety per IEC 60825-1
- Usability per IEC 60601-1-6 and IEC 62366
- Performance of Home Health Care Equipment per IEC 60601-1-11
- Performance of surgical, cosmetic, therapeutic and diagnostic equipment per IEC 60601-2-22
- Software verification and validation testing per IEC 62304/FDA Guidance
- Cleaning and Sterilization Testing – pass
- Storage and Transport Testing – pass

6. Clinical Performance Data

To validate the performance, safety, and effectiveness of the LMT-3000 and to demonstrate substantial equivalence to the predicate device, a randomized study was conducted comparing the LMT-3000 to standard steel lancets.

A total of 50 patients were evaluated between two visits, one week apart, for both the LMT-3000 and steel lancets. The sampling was done with the right hand first and the left hand subsequently for all subjects. During the first visit, half (25) of 50 subjects were sampled with the needle lancets on the right hand and with laser lancet on left hand. Another half of 50 subjects were sampled with the laser lancet on the right hand and with the needle lancet on left hand. During the second visit, the same procedures were done in the opposite order.

Analysis on the resultant glucose values indicated no significant difference in the glucose value between the needle lancet and laser lancet. There were no dropouts from either arm of the study group.

Some patients in the study reported less pain using the LMT-3000 compared to using the steel lancet for obtaining blood samples on some occasions.

7. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the differences, between the LMT-3000 device and the predicate device listed above, do not raise new types of questions regarding safety and effectiveness. Further, the LMT-3000 device utilizes the same type of technology as the predicate device. The LMT-3000, as designed and manufactured, is determined to be substantially equivalent to the above-listed predicate device.