Weifang KM Electronics Co., LTD
Andy Pang
General Manager
No. 7999 Health East Street, High-tech District
Weifang, 261000 CN

April 15, 2019

Re: K182924
Trade/Device Name: Diode Laser Treatment System
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: March 11, 2019
Received: March 13, 2019

Dear Andy Pang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.04.15 09:23:59 -04'00'

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

# Section 4 Indications for use

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)*

K182924

Device Name

Diode Laser Treatment System

Indications for Use *(Describe)*

The Diode Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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.

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# Section 5 510(k) summary

**I Submitter**

Device submitter: Weifang KM Electronics Co., Ltd.
No.7999 Health East Street, High-tech District, Weifang City, Shandong, China

Contact person: Andy PANG
General Manager
Phone: +86 136 0646 4486
Fax: +86-536-8885351
Email: 51050359@qq.com

Date of preparation: Oct 12th, 2018

**II Device**

Trade Name of Device: Diode Laser Treatment System
Models: KM200D, KM300D, KM600D, KM800D, KM900D
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery

**III Predicate Devices**

Trade Name of Device: Diode Laser Therapy Machine
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery
510(k) number: K161692

Trade Name of Device: Diode Laser Hair Removal System
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery
510(k) number: K141973

**IV Device description**

The Diode Laser Treatment System consists of the main unit and a hand piece. The system uses a diode laser as an active medium placed in an optical cavity to produce amplified beam at the wavelength of 808 nm. A microprocessor is used to control electronics for the front panel. A self-contained water cooling system is built into the power supply unit.

The device provides 36 working modes, which are six modes for men and six modes for women. The men or women mode includes face, armpit, arm, body, bikini, leg mode respectively for different treatment part. The diode laser operates in a pulsed mode with a fixed pulse width and fixed pulse duration of the pulse train for each mode. The number of pulses can be adjusted within the preset range.

**V Indications for use**

The Diode Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

**VI Comparison of technological characteristics with the predicate devices**

The Diode Laser Treatment System has the same technological characteristics and fundamental design as the predicate device. The subject device and the predicate devices are all designed for hair removal on different parts of the body. The differences between the subject device and predicate devices do not alter suitability of the proposed device for its intended use.

| **Device feature** | **Diode Laser Treatment System (subject device)** | **Diode Laser Therapy Machine FG 2000-B K161692** | **Diode Laser Hair Removal System K141973** |
|---|---|---|---|
| Product code | GEX | GEX | GEX |
| Regulation number | 21 CFR 878.4810 | 21 CFR 878.4810 | 21 CFR 878.4810 |
| Indications for use | The Diode Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin | The Diode Laser Therapy Machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin | The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin |

| | | | |
|---|---|---|---|
| | type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. | type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. | type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. |
| Operation principle | Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair. | Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair. | Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair. |
| Laser type | Diode laser | Diode laser | Diode laser |
| Laser classification | Class IV | Class IV | Class IV |
| Laser wavelength | 808nm | 808nm | 808nm |
| Spot Size | 1.44 $cm^2$ | 1.44 $cm^2$ | 1.44 $cm^2$ |
| Fluence | 2-120J/$cm^2$ | 2-120J/$cm^2$ | 1-120J/$cm^2$ |
| Frequency | 1-10Hz | 1-10Hz | 1Hz, 2Hz, 3Hz, 10Hz |
| Pulse Duration | 10-300ms | 9-143ms | 2.9-348ms |
| Power supply | 100-240V AC, 50/60Hz | AC110V/50-60Hz | AC110V, 60Hz |
| Dimension | KM200D 60*42*38cm | 42*63*54cm | 38*54*120cm |
| | KM300D 60*42*35cm | | |
| | KM600D 60*42*35cm | | |
| | KM800D 60*42*40cm | | |
| | KM900D 55*42*30cm | | |
| Weight | 35kg | 30kg | 55kg |
| Patient contact material | Sapphire in handpiece and handpiece tip (stainless steel) | Sapphire in handpiece and handpiece tip (stainless steel) | Sapphire in handpiece and handpiece tip (stainless steel) |
| Biocompatibility | Comply with ISO10993-1 | Comply with ISO10993-1 | Comply with ISO10993-1 |

| | | | |
|---|---|---|---|
| Electrical Safety | Comply with IEC60601-1, IEC60601-2-22 | Comply with IEC60601-1, IEC60601-2-22 | Comply with IEC60601-1, IEC60601-2-22 |
| EMC | Comply with IEC60601-1-2, | Comply with IEC60601-1-2, | Comply with IEC60601-1-2, |
| Laser safety | Comply with IEC60825-1, IEC60601-2-22 | Comply with IEC60825-1, IEC60601-2-22 | Comply with IEC60825-1, IEC60601-2-22 |

**VII Performance data**

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

**Biocompatibility testing**

Biocompatibility of the Laser Treatment System was evaluated in accordance with ISO 10993-1:2009 for the body contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Laser Treatment System. The system has been tested to comply with the following standards:

- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2007, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment;
- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

**VIII Conclusion**

The Diode Laser Treatment System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.