



Food and Drug Administration
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Beijing Sincoheren Science And Tech. Development Co., Ltd
% Mr. Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technology Service Co., Ltd
7th Floor, Jingui Business Building, No.982 Congyun Rd.
Baiyun District
Guangzhou, 510420 CN

Re: K152898
Trade/Device Name: Diode Laser Therapy Systems
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: September 20, 2015
Received: October 1, 2015

Dear Mr. Gu:

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,

Jennifer R. Stevenson -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

Indications for Use

510(k) Number (if known)

K152898

Device Name

Diode Laser Therapy Systems, Model SDL-B

Indications for Use (Describe)

The Diode Laser Therapy Systems are intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI). 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.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

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II. DEVICE

Name of Device: Diode Laser Therapy Systems, Model SDL-B

Common/Usual Name: Diode Laser Therapy Systems

Classification Names: Powered Laser Surgical Instrument (21 CFR 878.4810)

Regulation Class: II

Product Code: GEX

III. PREDICATE DEVICE



Emvera Diolux, K123257

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Diode Laser Therapy Systems mainly consist of console, treatment hand piece and a foot switch. The diode laser emits wavelength of 808nm from the treatment hand piece, the wavelength effectively penetrates deep into and absorbed by the target chromophore. The adequate pulse duration, energy density and epidermal cooling ensure an adequate thermal damage to the target tissue without damaging the surrounding tissue to achieve effective hair removal.

V. INDICATION FOR USE

The Diode Laser Therapy Systems are intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI).

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. SUBSTANTIAL EQUIVALENCE

| Specification | Predicate device | Proposed device | Discussion of Differences |
|---------------------|---|--|---------------------------|
| <i>K number</i> | K123257 | -- | |
| <i>Manufacturer</i> | Emvera Technologies, LLC. | Beijing Sincoheren Science and Technology Development Co., Ltd. | |
| <i>Device name</i> | Emvera Diolux | Diode Laser Therapy Systems | |
| <i>Intended Use</i> | The Emvera Diolux is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI). 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. | The Diode Laser Therapy Systems are intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI). 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. | same |



| Specification | Predicate device | Proposed device | Discussion of Differences |
|---------------------------------|---|---|--|
| <i>Wavelength (nm)</i> | 808 | 808 | Same |
| <i>Output power (W)</i> | 600 | 500 | Less than the output of predicate device. |
| <i>Fluence (Energy Density)</i> | <120 J/cm ² | <120 J/cm ² | Same |
| <i>Pulse Duration</i> | 5ms-625ms | 5ms-400ms | The maximum pulse duration is smaller than the predicate device. |
| <i>Frequency</i> | 1Hz-10Hz | 1Hz-10Hz | Same |
| <i>Spot Size</i> | 12mm × 12mm | 12mm × 10mm | Smaller than the predicate device. |
| <i>Material</i> | Sapphire | Sapphire | Same |
| <i>Cooling</i> | Water cooling | Water cooling | Same |
| <i>Anatomical Sites</i> | Axilla, Face, bikini, Upper limb and lower limb, brow, upper lip, neck, chest, back | Axilla, Face, bikini, Upper limb and lower limb | Less than the predicate device. |

VII. PERFORMANCE DATA

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

Biocompatibility testing

The biocompatibility evaluation for the device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The laser output window of testing included the following tests:



- Cytotoxicity
- Sensitization
- Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The system complies with the IEC 60601-1 and IEC 60825-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure of latent design flaw could directly result in minor injury to the patient or operator.

VIII. CONCLUSION

The Diode Laser Therapy Systems and its application comply with standards as detailed in section 9, 11 and 17 of this premarket notification. Non-clinical tests determined that the Diode Laser Therapy Systems to be as safe, as effective and performance is substantially equivalent to the predicate device.