May 20, 2022

Beijing LaserTell Medical Co., Ltd.
Mr. Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K220381
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: April 18, 2022
Received: April 22, 2022

Dear Ray Wang:

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,

Purva Pandya
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220381

Device Name
Diode Laser Therapy Systems

Indications for Use *(Describe)*
The Diode Laser Therapy Systems 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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The assigned 510(k) Number: K220381

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation:2022/05/18

2. Sponsor Identification

Beijing LaserTell Medical Co., Ltd.

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Diode Laser Therapy Systems
Common Name: Powered Laser Surgical Instrument
Model(s): AlexMED Pro

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Indication For Use Statement:

The Diode Laser Therapy Systems 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.

5. Device Description

Diode Laser Therapy Systems is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI);

The Diode Laser Therapy Systems utilize a semiconductor diode with invisible infrared radiation as a laser source to emit 808nm wavelength laser which is absorbed by melanin. The laser power is delivered to the treatment area via laser handpiece. The emission laser is activated by a foot-switch.

The Diode Laser Therapy Systems utilize the principle of photoepilation for hair removal. The Photoepilation is a technique for removal of unwanted hair by thermal destruction of the hair follicle and its reproductive system (stems cells). The heat is caused by selective absorption of electromagnetic radiation emitted by laser light sources. As melanin is the main chromophore existing in hair follicles, so the melanin could absorb the energy from the laser, which would result in temperature rapid increase, then the hair follicle and its reproductive system (stems cells) would be destroyed by increased high temperature without damage epidermis and the surrounding normal tissue.

6. Identification of Predicate Device(s)

510(k) Number: K180353
Product Name: Diode Laser Hair Removal Device
Manufacturer: Zhengzhou PZ Laser Slim Technology Co., Ltd

7. Substantially Equivalent (SE) Comparison

Table 7-1 General Comparison

Item	Proposed Device	Predicate Device	Remark
Device Name	Diode Laser Therapy Systems	Diode Laser Hair Removal Device	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	SAME
Class	II	II	SAME
Product Code	GEX	GEX	SAME
Indication for use	The Diode Laser Therapy Systems 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.	The Diode Laser Hair Removal device 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.	SAME

Table 7-2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Laser Type	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser Wavelength	808nm±2nm	808nm	SAME
Spot Size	15mm×15mm	1.44cm²	Analysis 1
Fluence	1-100J/cm²	1-100J/cm²	SAME
Frequency	1-10Hz	1-20 Hz	Analysis 2
Pulse Duration	1-300ms	10~400ms	Analysis 3
Power Supply	110 Va.c.60Hz 2000W	AC 110V-230V/50-60Hz 2000VA	Analysis 4
Dimension	460mm×390mm×1230mm	560mm×380mm×1180mm	Analysis 5
Weight	75Kg	60Kg	Analysis 5

Analysis：

Analysis 1: #Spot size

The proposed device is different in Spot Size from the predicate, Spot size only affects the area of treatment, not affect the therapeutic effect. Non-clinical tests about the spot size have been conducted on the proposed device and the results show that the proposed device meets the requirements. Therefore, this difference will not affect the substantially equivalency.

Analysis 2: #Frequency

The frequency for the proposed device is different from the predicate device. However, the frequency of the proposed device is within the range of that of the predicate device, which can justify that the difference in the parameter of frequency will not raise new safety issues of the proposed device. And the bench tests conducted on the proposed device is same with the predicate device, the results of which could support the substantially equivalency with predicate device.

Analysis 3: #Pulse Duration

The proposed device only has slight difference in pulse duration with the predicate device. The frequency of the proposed device is within the range of that of the predicate device, which can justify that the difference in the parameter of Pulse duration will not raise new safety issues of the proposed device. So the slight difference is considered to have no effect on effectiveness and safety. And the bench tests conducted on the proposed device is same with the predicate device, the results of which could support the substantially equivalency with predicate device.

Analysis 4: # Power Supply

The Power Supply of proposed device is different with the predicate device, but the proposed device has been conducted as IEC 60601-1 and IEC 60601-1-2, the results shown that, there is no effect the effectiveness and safety.

Analysis 5: #Dimension/ Weight

The proposed device is different in dimension and weight from the predicate device. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference will not affect the substantially equivalency.

Table 7-3 Safety Comparison

Item	**Proposed Device**	**Predicate Device**	**Remark**
EMC, Electrical and Laser Safety			

Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SAME
Patient Contact Materials and Biocompatibility			
Patient Indirect Contact Materials	Tip of Handle (6061 Aluminum & Sapphire) Plastic shell (Acrylonitrile Butadiene Styrene)	Sapphire	Analysis 6
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SAME
Sensitization	No evidence of sensitization	No evidence of sensitization	SAME
Irritation	No evidence of irritation	No evidence of irritation	SAME

Analysis 6 # Patient Indirect Contact Materials

The patient contact material for the proposed device is different from the predicate device. However, biocompatibility test has been conducted on the proposed device and the test result can meet the requirements of ISO 10993 series standard. Therefore, this difference will not affect safety and effectiveness of the proposed device.

8. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1-2:2014 Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
IEC 60601- 1:2005+CORR.1:2006+CORR.2:2007+A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-2-22:2007 + A1:2012 +A2:2019 Medical Electrical Equipment - Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60825-1:2014 (Third Edition) Safety of laser products - Part 1: Equipment classification, and requirements
ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Diode Laser Therapy Systems (AlexMED Pro) is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Diode Laser Hair Removal Device cleared under K180353.