July 28, 2021

Zhengzhou Bestview St Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, BeiJing 102401
China

Re: K211335
Trade/Device Name: Diode Laser Machine, Model: BM-100
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 28, 2021
Received: May 3, 2021

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)*

K211355

Device Name

Diode Laser Machine
Model: BM-100

Indications for Use *(Describe)*

The Diode Laser Machine (Model: BM-100) 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.

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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

   07/27/2021

2. Applicant Name and Address

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3. Contact Person Information

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4. Submission Correspondent

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510(k) Summary

5. Identification of Proposed Device
   Trade Name: Diode Laser Machine
   Common Name: Powered Laser Surgical Instrument
   Model(s): BM-100
   Classification Name: Powered Laser Surgical Instrument
   Classification: II;
   Product Code: GEX;
   Regulation Number: 21 CFR 878.4810;
   Review Panel: General& Plastic Surgery;

6. Identification of Primary Predicate
   510(k) Number: K162659
   Product Name: Diode Laser Hair Removal System
   Manufacturer: Shandong Huamei Technology Co., Ltd.

7. Device Description
   The proposed device incorporates a diode laser that emits invisible infrared laser radiation centered on a wavelength of 808 nm. Main components of the device include the laser console, liquid crystal display (LCD) touchscreen control panel, and laser handpiece. The device emits pulses of the 808 nm infrared laser emissions at pulse widths, repetition frequency, and energy levels, conductive to hair removal. The device incorporates water cooling, air cooling fan, and switches/buttons to control the laser output. The device is powered via an alternating current power source. Specification for the device are provided below.

8. Indication For Use

   The Diode Laser Machine (Model: BM-100) 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.

9. Substantially Equivalent (SE) Comparison

Table 3 General Comparison

ITEM	Proposed Device	Predicate Device (K162659)	Remark
Product Code	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	SAME
Where used	Hospital	Hospital	SAME
Intended Use	The Diode Laser Machine (Model:	The Diode Laser Hair Removal System is	SAME

	BM-100) 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.	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.	
Configuration	Main Unit	Main Unit	SAME
	Handpiece	Handpiece	SAME
Principle of Operation	Diode Laser	Diode Laser	SAME

Table 4 Performance Comparison

ITEM	Proposed Device	Predicate Device (K162659)	Remark
Laser Type	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser wavelength	808 nm	808 nm	SAME
Spot Size	2.25 cm2 (15mm x 15mm)	1.44 cm2	
Fluence	0-120 J/cm2	1-120J/cm2	Similar
Frequency	1-10 Hz	05-15Hz	Similar
Pulse Duration	10-400 ms	5-400 ms	Similar
Power Supply	220/110 VAC/50Hz-60Hz	AC 110V/60Hz	SAME
Dimension	112 cm x 42 cm x 60cm	450mm x 550mm x 350mm	
Weight	63 kg	52kg	

Table 5 Safety Comparison

Item	Proposed Device	Predicate Device (K162659)	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 Contact Materials	handpiece	handpiece	SAME
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-1	SAME
Sensitization	No evidence of sensitization		
Irritation	No evidence of irritation		

510(k) Summary

10. 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 conform to 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 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements.
- 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.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity
- Software Validation & Verification Test

11. Clinical Testing

No clinical study is included in this submission.

12. Conclusion

The proposed device utilizes technological characteristics that are the same or are similar to the predicate device. The proposed device's technological characteristics do not raise new types of questions regarding safety and effectiveness, and performance testing conducted supports that the device can be used safety and effectively for the proposed indication for use above. Based on the comparison and analysis above, the proposed device is considered to be Substantially Equivalent (SE) to the predicate device.