April 26, 2021

Beijing HuaCheng Taike Technology Co., Ltd.
% Hui Liu
Official Correspondent
Beijing Believe Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K210663
Trade/Device Name: Dermatological Diode Laser 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: February 27, 2021
Received: March 5, 2021

Dear Hui Liu:

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 and Part 809); 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)*
K210663

Device Name
Dermatological Diode Laser Systems

Indications for Use *(Describe)*
The Dermatological Diode Laser Systems(Model:CM01D/CM02D) 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.

The assigned 510(k) Number: K210663

1. Date of Preparation

   04/15/2021

2. Sponsor

   Beijing HuaCheng Taike Technology Co., Ltd.

   5102P,Floor1,Building5,No.17Yunshannanlu Road, Tongzhou Industrial Development Zone,Tongzhou district, 101113 Beijing, P.R. China

   Contact Person: Li Yi

   Position: General Manager

   Tel: +86 15810861388

   Fax: +8610 61592593

   Email: alex@cosmedplus.com

3. Submission Correspondent

   Contact Person:

   Mr. Ray Wang(Primary)

   Tel: +86-18910677558

   Fax: +86-10-52214696

   Email: ray.wang@believe-med.com

   Ms. Hui Liu（Secondary）

   Tel: +86-15922145259

   Fax: +86-10-52214696

   Email: hui.liu@believe-med.com

   Beijing Believe Technology Service Co., Ltd.

   Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China,102401

4. Identification of Proposed Device

Trade Name: Dermatological Diode Laser Systems
Common Name: Powered Laser Surgical Instrument
Model(s): CM01D/CM02D

Regulatory Information:
Classification Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;

Indication For Use:

The Dermatological Diode Laser Systems(Model:CM01D/CM02D) 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

The Dermatological Diode Laser 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 s laser handpiece. The emission laser is activated by a foot-switch.

There are 2 models included,CM01D,CM02D, the two models have same mechanism of action, principle and specification, only difference is the configuration. The detailed difference shown as following:

Table 1 The Difference of Models

	CM01D	CM02D
Display	15.6" color touch LCD screen	4.3" color touch LCD screen
Treatment laser spot	10 × 30 mm	9× 12 mm
Pulse width	15-400 ms（continuously adjustable）	35-400 ms（continuously adjustable）
Energy density	05-100J/ cm2（continuously adjustable）	03-30J/ cm2（continuously adjustable）
Pulse frequency	1-10Hz	1-3Hz
Size	63*52*46cm	49*44*139cm
Weight	75Kg	3Kg

6. Identification of Predicate Device

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

Reference Device
510(k) Number: K142845
Product Name: SILKPRO Laser Hair Removal System
Manufacturer: Wuhan Lotuxs Technology Company, Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was to be as safe, as effective, and perform as well as the legally marketed predicate devices.. The test results demonstrated that the proposed device complies with the following standards:

- AAMI ES60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Safety And Essential Performance
- IEC 60601-2-22:2007 + A1:2012, 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, 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 – Electromagnetic Compatibility
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1
- Software Validation & Verification Test

According to "guidance for the content of premarket submissions for software contained in medical devices" issued by FDA, software verification and validation activities were carried out. Verification and validation activities include the verification and validation of product function, product performance and product interface. All verification and validation activities can meet the specified requirements, and the product software is safe and effective.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Comparison with Predicate and Reference Devices

Table 2 General Comparison

ITEM	Proposed Device	Predicate Device（K180353）	Reference Device (K142845)	Remark
Product Code	GEX	GEX	OHT	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Class	2	2	2	Same
Indication For Use	The Dermatological Diode Laser Systems(Model:CM01D/CM02D) 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.	SILKPRO is an over-thecounter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.	Same
Configuration	Main Unit	Main Unit	/	Same
	Handpiece	Handpiece	/	Same
	Foot Control	Foot Control	/	Same
Principle of Operation	Diode Laser	Diode Laser	Diode Laser	Same

Table 3 Performance Comparison

ITEM	Proposed Device	Predicate Device（K180353）	Reference Device (K142845)	Remark
Laser Type	Diode Laser	Diode Laser	Diode Laser	Same
Laser Classification	Class IV	Class IV	Class IV	Same
Laser wavelength	808 nm	808 nm	810 nm	Same
Spot Size	CM01D:10 × 30 mm CM02D:9× 12 mm	1.44 cm^2	9mm×9mm（0.81cm^2）	Analysis 1
Fluence	CM01D:5-100J/ cm2 CM02D:03-30J/ cm2	1-100J/ cm^2	5-25J/cm^2	Analysis 2
Frequency	CM01D: 1 – 10 Hz; CM02D: 1 – 3 Hz	1-20Hz	/	Analysis5
Pulse Duration	CM01D:15-400 ms CM02D:35-400 ms	10-400ms	/	Similar
Power Supply	AC 110V/60Hz	AC 110V/60Hz	AC100～240V, 50/60Hz	Same
Dimension	CM01D:65cmX65cmX123cm CM02D:253mm*210mm*193mm	560mm x 380mm x1 180mm	/	Analysis 3
Weight	CM01D:75KG CM02D:3kg	60kg	/	Analysis 4

Analysis 1

The proposed device is different in Spot Size from the predicate, Spot size only affects the area of treatment, not affect the therapeutic effect.Therefore, this difference will not affect the safety and effectiveness.

Analysis 2

The proposed device is different in fluence from the predicate device, the difference is very slight. Fluence of the proposed device is within the range of the predicate and reference devices.And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test ,IEC60825-1 test, the safety and performance of the product can be ensured. So the proposed device is determined to be as safe, as effective, and performs as well as the legally marketed predicate devices.

Analysis 3/ 4

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 safety and effectiveness.

Analysis 5

The proposed device is different in Frequency from the predicate device, the frequency is the number of times light is emitted in a second.The Frequency of the proposed device is within the range of the

predicate device.And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test ,IEC60825-1 test, the safety and performance of the product can be ensured. therefore, this difference will not affect the safety and effectiveness.

Table 4 Safety Comparison

Item	Proposed Device	Predicate Device（K180353）	Reference Device (K142845)	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	Comply with IEC 60601-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2	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	Comply with IEC 60601-2-22, IEC 60825	Same
Patient Direct/Indirect Contact Materials and Biocompatibility				
Patient Direct/Indirect Contact Materials	Tip of Handle（6061 Aluminium &Quartz） Device Housing（Acrylonitrile Butadiene Styrene)	Sapphire in handpiece	Stainless steel and Sapphire in handpiece	Analysis6
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-1	Same
Sensitization	No evidence of sensitization	No evidence of sensitization		
Irritation	No evidence of irritation	No evidence of irritation		

Analysis 6:

The proposed device is different in Patient Indirect Contact Materials from the predicate device, to confirm that the components and materials contained in the finished device as identified above are not adverse to human tissue, the biocompatibility testing was performed in accordance with ISO 10993-1: 2009 and guidance document entitled Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing.The results for the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device, therefore, this difference will not affect the safety and effectiveness.

10. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be as safe, as effective, and performs as well as the legally marketed predicate devices.