May 21, 2020

Shangdong Huamei Technology Co., Ltd.
% 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: K200751
Trade/Device Name: Photodynamic Therapy (PDT) Equipment
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 20, 2020
Received: March 23, 2020

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,

Colin Kejing Chen
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200751

Device Name
Photodynamic Therapy (PDT) Equipment

Indications for Use *(Describe)*
The Photodynamic Therapy (PDT) Equipment use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.
The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
The red light (630nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.
The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K200751

K200751 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: K200751

1. Date of Preparation: 05/18/2020

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Photodynamic Therapy (PDT) Equipment
Common Name: Powered Laser Surgical Instrument
Model(s): HM-PDT 900

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 Photodynamic Therapy (PDT) Equipment use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.
The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
The red light (630nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.
The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Device Description:
The Photodynamic Therapy (PDT) Equipment HM-PDT 900 is a vertical device which uses specific wavelengths of light, produced by LEDs (Light emitting diodes), to manage aesthetic conditions. The device produces light in the red light region of the spectrum (630±15nm), in the blue light regions of the light spectrum (415±15nm) and infrared light region of light spectrum (835±15nm).
Five sets of LEDs panels are available for the device.

5. Identification of Predicate Device(s)

K190938
Phototherapy System
Shanghai Apolo Medical Technology Co., Ltd.

6. 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:

a) IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

b) IEC 60601-1:2005/A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

c) IEC60601-2-57:2011, Medical electrical equipment -- Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

d) IEC 62471:2006 Photobiological safety of lamps and lamp systems.

e) Software Verification and Validation Testing

f) Bench Testing (Energy density output accuracy, Wavelength accuracy)

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 7-1 General Comparison

ITEM	Proposed Device	Predicate Device (K190938)	Remark
Product Code	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	II	II	SAME
Intended Use	The Photodynamic Therapy (PDT) Equipment use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The red light (630nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	Phototherapy Systems use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris The red light (630nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	SAME

Table 7-2 Performance Comparison

ITEM	Proposed Device	Predicate Device (K190938)	Remark
Wavelength (nm)	Red light 630nm±15nm Blue light 415nm±15nm Infrared light 835nm±15nm	Red light 630±15nm; Blue light 415±5nm; NIR light 835±10nm	SAME
Panels Type	5panel: 300 EALEDs. The panels may emit the three light (red, blue, infrared)	3panel: 180EA LEDs 4 Panel: 240 EALEDs. The panels may emit the three light (red, blue, infrared)	Analysis
Light frequency	200Hz	200Hz	SAME
LED power	Each LED lamp bead has 3 diodes that emit different colors, the Energy power of a diode is 3W.	Each LED lamp bead has 3 diodes that emit different colors, the Energy power of a diode is 3W.	SAME
Maximum power density in mW (J)	(1) Red light: 115mW/cm2 (242J/cm2), (2) Blue light: 120mW/cm2(180J/cm2), (3) IR: 70mW/cm2(147J/cm2)	(1) Red light: 115mW/cm2 (242J/cm2), (2) Blue light: 120mW/cm2(180J/cm2), (3) IR: 70mW/cm2(147J/cm2)	SAME
Treatment area	1410cm2	756cm2 and 1008cm2	Analysis
Treatment time	20 minutes (recommended Treatment Time)	20 minutes (recommended Treatment Time)	SAME
Numbers of LEDs	5 panels:300EA	3 panels: 180EA, 4 panels: 240EA.	Analysis
Working distance	10~15cm	10~15cm	SAME
Power supply	AC 100-240V 50/60Hz 500VA	AC 100-240V 50/60Hz 10A	SAME
Dimension	638mm×243mm×1560mm (Host) 494mm×346mm×69（LEDs Panels）	500mm[H]× 500[W]× 1350[D]	Analysis
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-1-2	Comply with IEC 60601-1 and IEC 60601-1-2	SAME
Radiation Safety	Comply with IEC 60601-2-57	Comply with IEC 60601-2-57	SAME
Photobiological safety	Comply with IEC 62471	Comply with IEC 62471	SAME

Analysis:

The proposed device has different panel number, diode number of each LED, LED number, and treatment area than predicate device, but the difference does not affect the output energy for treatment. Therefore, the slight difference is considered to have no effect on effectiveness and safe.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.