Shanghai Apolo Medical Technology Co., Ltd.
% Felix Li
Regulatory Affairs
4F, Building A
No. 388 Yindu Road
Xuhui District
Shanghai, 200231 China

June 26, 2019

Re: K190938
Trade/Device Name: Phototherapy System
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 4, 2019
Received: April 10, 2019

Dear Felix Li:

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,

Neil R.P. Ogden, MS
Acting Assistant Director,
THT4A3: Light Based Devices Team
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190938

Device Name
Phototherapy Systems

Indications for Use *(Describe)*
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.

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

I Submitter

Shanghai Apolo Medical Technology Co., Ltd.
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Establishment Registration Number: 3007120647

Contact person: Felix Li
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II Proposed Device

Trade Name of Device:	Phototherapy Systems
Common name:	Powered Laser Surgical Instrument
Regulation Number:	21 CFR 878.4810
Regulatory Class:	Class II
Product code:	GEX
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k) Number:	K120460
Trade name:	SMARTLUX
Common name:	Visible and Infrared Light Source
Classification:	Class II
Product Code:	GEX
Manufacturer	Medmix Co, Ltd.

IV Device description

The Phototherapy Systems HS-770 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). Three or four sets of LEDs panels are available for the device.

V Indication for use

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.

VI Comparison of technological characteristics with the predicate devices

Item	**Subject device**	**Predicate device (K120460)**
Product name	Phototherapy System (HS-770)	SMARTLUX
Product Code	**GEX**	**GEX**
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II
Indication for use	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	633nm wave length: Dermatology for treatments of superficial, benign vascular, and pigmented lesion 415nm wave length: dermatological condition and specifically indicated to treatment moderate inflammatory acne vulgaris 830nm wave length: 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

	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.	applied.
Power supply	AC 100-240V 50/60Hz 10A	AC 100-240V 47-63Hz
wavelength	Red light 630nm±15nm Blue light 415nm±15nm Infrared light 835nm±15nm	Red light 633nm±6nm Blue light 415nm±5nm Infrared light 830nm±5nm
Panels Type	• 3 panel: 180EA LEDs 4 Panel: 240 EA LEDs. • The panels may emit the three light (red, blue, infrared) individual or in combination	Four type, each head type has only one light. • Red • Blue • Infrared • Red+Infrared
Light frequency	200Hz	unknown
Output Power	Each LED lamp bead has 4 diodes that emit different colors, the energy power of a diode is 3W.	unknown
Maximum power density in mW	(1) Red light: 115mW/cm^2, (2) Blue light: 120mW/cm^2, (3) IR: 70mW/cm^2, (4) Red/IR: 120mW/cm^2 (5) Blue/IR: 150mW/cm^2	(1) Red: 115mW/cm^2 (2) Blue: 75mW/cm^2 (3) IR 60W/cm^2 (4) Red/IR: 75mW/cm^2
Standard does in Joules	(1) Red light: 138J/cm^2, (2) blue light: 144J/cm^2, (3) IR: 84J/cm^2, (4) Red/IR: 144J/cm^2 (5) Blue/IR: 180J/cm^2	(1) Red: 138J/cm^2 (2) Blue: 90J/cm^2 (3) Infrared: 72J/cm^2 (4) Red/IR: 90J/cm^2
Adjustable dose range	(1) Red light: 1-242J/cm^2, (2) blue light: 1-180J/cm^2, (3) IR: 1-147J/cm^2, (4) Red/IR: 1-144J/cm^2, (5) Blue/IR:1-180J/cm^2	(1) Red light: 1-276J/cm^2, (2) blue light: 1-180J/cm^2, (3) IR: 1-144J/cm^2, (4) Red/IR: 1-180J/cm^2

Treatment area	756cm^2 and 1008cm^2	779cm^2
Treatment time	20minutes (recommended Treatment Time)	20minutes(recommended standard dose)
Numbers of LEDs	3 panels: 180EA, 4 panels: 240EA.	Red: 2400EA, Blue: 1500EA Infrared:800EA Red+IR: • Red: 700EA • IR: 500EA
Working distance	10~15cm	Unknow
Operation interface	Display Screen	Display Screen
Dimension	500mm[H]× 500[W]× 1350[D]	390mm[H]×540mm[W]×840 mm[D]
Safety classification	Class I	Class I
Software	Yes	Yes

VII Non-Clinical Testing

A battery of tests to verity that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility

IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-2-57:2011 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.

VIII Clinical Testing

It is not applicable.

IX Conclusion

Base on the performance testing and validation studies that the subject device is substantially equivalent to the predicate device.