September 20, 2023

Shenzhenshi Sincoheren S&T Development 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: K231894
Trade/Device Name: LED Spectrum therapy instrument
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, ILY
Dated: June 28, 2023
Received: June 28, 2023

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2023.09.20
16:09:23 -04'00'

Tanisha Hithe, MS, MHS
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)*
K231894

Device Name
LED Spectrum therapy instrument (Model: PDT-I, PDT-J, PDT-K, PDT-L, PDT-M)

Indications for Use *(Describe)*
The LED Spectrum therapy instrument includes five models, which are PDT-I, PDT-J, PDT-K, PDT-L, PDT-M.

PDT-I:
Blue (420±10nm) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.
Combination of Red (630±10nm) and Blue (420±10nm) is indicated for the treatment of mild to moderate inflammatory acne.

PDT-J:
Combination of Yellow (590±10nm) and Infrared (825±10nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.
Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

PDT-K:
Blue (420±10nm) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
Combination of Red (630±10nm) and Blue (420±10nm) is indicated for the treatment of mild to moderate inflammatory acne.

PDT-L:
Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

PDT-M:
Combination of Yellow (590±10nm) and Infrared (825±10nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; 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

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

The assigned 510(k) Number: K231894

1. Date of Preparation: 09/01/2023

2. Sponsor

Shenzhenshi Sincoheren S&T Development Co.,Ltd
Floor 4, No.2 Plant, No. 14 Zhongxing Road, Xiuxin Community, Kengzi Street Office, Pingshan District, Shenzhen City, China, 518118
Contact Person: Zhongzhou Li
Position: General manager
Tel: +86-15810585973
Fax: +86-755-84235904
Email: 1620096810@qq.com

3. Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China, 102401
Contact Person: Ray Wang
Position: General Manager
Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

4. Proposed Device Identification

Trade Name: LED Spectrum therapy instrument
Common Name: Powered Laser Surgical Instrument
Model(s): PDT-I, PDT-J, PDT-K, PDT-L, PDT-M
Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II

Product Code: GEX, ILY

Regulation Number: 21 CFR 878.4810 / 21 CFR 890.5500

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Review Panel: General & Plastic Surgery / Physical Medicine

Indication For Use Statement:

The LED Spectrum therapy instrument includes five models, which are PDT-I, PDT-J, PDT-K, PDT-L, PDT-M.

PDT-I:

Blue (420±10nm) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Combination of Red (630±10nm) and Blue (420±10nm) is indicated for the treatment of mild to moderate inflammatory acne.

PDT-J:

Combination of Yellow (590±10nm) and Infrared (825±10nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.

Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

PDT-K:

Blue (420±10nm) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

Combination of Red (630±10nm) and Blue (420±10nm) is indicated for the treatment of mild to moderate inflammatory acne.

PDT-L:

Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

PDT-M:

Combination of Yellow (590±10nm) and Infrared (825±10nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.

5. Device Description

The LED Spectrum therapy instrument is a portable device which uses specific wavelengths of light, produced by light emitting diodes (LEDs).

The device produces light in the following regions of the light spectrum:

- Red (630±10nm)
- Blue (420±10nm)
- Yellow (590±10nm)
- Infrared (825±10nm)

This device's main components are the stand, the head, color touch screen, and the power supply. User interface software allows the operator to access and control all device functions.

6. Predicate Device Identification

Primary Device:
510(k) Number: K221083
Product Name: Phototherapy Unit
Manufacturer: MEDMIX Co., Ltd.

Predicate Device:
510(k) Number: K180900
Product Name: LED Light Therapy Device
Model: KN-7000C2
Manufacturer: Xuzhou Kernel Medical Equipment Co., Ltd.

7. 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: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020 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

- IEC 62471: 2006 Photobiological safety of lamps and lamp systems
- ISO 14971: 2019 Medical devices - Application of risk management to medical devices

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison

ITEM	**Proposed Device**	**Primary Device (K221083)**	**Predicate Device (K180900)** Model: KN-7000C2	Remark
Product Code	GEX, ILY	GEX, ILY	OLP	Analysis 1
Regulation No.	21 CFR 878.4810 / 21 CFR 890.5500	21 CFR 878.4810 / 21 CFR 890.5500	21 CFR 878.4810	SAME
Class	2	2	2	SAME
Indication for Use	The LED Spectrum therapy instrument includes five models, which are PDT-I, PDT-J, PDT-K, PDT-L, PDT-M. PDT-I: Blue (420±10nm) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. Combination of Red (630±10nm) and Blue (420±10nm) is indicated for the treatment of mild to moderate inflammatory acne. PDT-J: Combination of Yellow (590±10nm) and Infrared (825±10nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.	Blue (415-425nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. Red (630-640nm) and Infrared (820-830nm) Combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. Combination of Infrared (820-830nm) and Yellow (585-595nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.	The LED Light Therapy Device is indicated for the treatment of mild to moderate inflammatory acne.	SAME

	Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. PDT-K: Blue (420±10nm) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. Combination of Red (630±10nm) and Blue (420±10nm) is indicated for the treatment of mild to moderate inflammatory acne. PDT-L: Combination of Red (630±10nm) and Infrared (825±10nm) is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. PDT-M: Combination of Yellow (590±10nm) and Infrared (825±10nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.			
OTC or Prescription Use	Prescription Use	Prescription Use	OTC	Difference Analysis 2
Configuration	Portable	Portable	Handheld	Difference Analysis 3
Components	Bracket, Therapeutic head, Operation panel, Power box	Stand, Head, Color touch screen, Power supplier	/	SAME

Wavelength	Red: 630±10nm Blue: 420±10nm Infrared: 825±10nm Yellow: 590±10nm	RED: 630-640nm BLUE: 415-425nm IR: 820-830nm YELLOW: 585-595nm	Red: 633±6nm Blue: 415±5nm	SAME
Effective irradiance	Adjustable 5 levels Red: 20~45 mW/cm^2 Blue: 10~40 mW/cm^2 Infrared: 10~30 mW/cm^2 Yellow: 10~18 mW/cm^2 Combination of Red and Infrared: 30~75 mW/cm^2 Combination of Red and Blue: 30~85mW/cm^2 Combination of Yellow and Infrared: 20~48 mW/cm^2	Adjustable 5 levels Red : 26-50 mW/cm^2 Blue : 9~41 mW/cm^2 IR: 11~28 mW/cm^2 Yellow: 12-20mW/cm^2 Combination of Red and Infrared: 37~78 mW/cm^2 Combination of Yellow and Infrared: 23~48 mW/cm^2	Red light: 65±5 mW/cm^2 Blue light: 35±5 mW/cm^2 Combination of Red and Blue: 110±10 mW/cm^2	Difference Analysis 4
Operation interface	Continuous operation	Continuous operation	Continuous operation	SAME
Number of LEDs in each panel	156	288	8	Difference Analysis 5
Pulse repetition rate (Hz)	1Hz, 5Hz, 10Hz, 50Hz, 100Hz, 150Hz, 200Hz and 500Hz	1Hz, 5Hz, 10Hz, 50Hz, 100Hz, 150Hz, 200Hz and 500Hz	/	SAME
Max fluence /energy density	Blue: 54 J/cm^2 at 20 minutes treatment time Combination of Red and Infrared: 90 J/cm^2 at 20 minutes treatment time Combination of Yellow and Infrared: 57.6 J/cm^2 at 20 minutes treatment time	Blue: 49.2 J/cm2 at 20 minutes treatment time Combination of Red and Infrared: 93.6 J/cm^2 at 20 minutes treatment time Combination of Yellow and Infrared: 57.6 J/cm^2 at 20 minutes treatment time	/	Difference Analysis 6
	Combination of Red and Blue: 15.3 J/cm^2 at 3 minutes treatment time	/	Combination of Red and Blue: 13.2 J/cm^2 at 2	

			minutes treatment time	
Treatment time	1-30 min adjustable (Recommended 20 minutes for Single Blue Type, Combination of Red and Infrared Type, Combination of Yellow and Infrared Type); (Recommended 3 minutes for Combination of Red and Blue Type)	20 min	Recommended for 2 min	Difference Analysis 7
Lamps working distance	7cm±2cm	20cm	/	Difference Analysis 8
Standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 ISO 10993-1 ISO 10993-5 ISO 10993-10	Difference Analysis 9
Microprocessor control	Yes	Yes	Yes	SAME
Continuous / Pulsed Output	Continuous and Pulsed	Continuous and Pulsed (up to 500 pulses per second)	Continuous and Pulsed	SAME

Analysis 1/2:

The proposed device is different in Product Code from the predicate device (K180900). The intended use of the proposed device and predicate device (K180900) is the same, but the Type of Use is different. The predicate device is OTC device, the proposed device is Prescription Use device. Compared with OTC, the risk of Prescription Use is lower, so we believe that this difference will not raise any risks, both the proposed device and predicate device (K180900) are safe and effective.

Analysis 3:

The proposed device is different in Configuration from the predicate device (K180900). However, the configuration difference are just in physical specification and this difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 4:

The proposed device has similar Effective irradiance with the primary predicate device (K221083) in Red, Blue, Infrared, Yellow light source and also similar in Combination of Red and Infrared type and Combination of Yellow and Infrared type.

For the Combination of Red and Blue type, the proposed device is different with the secondary predicate device (K180900). From the comparison above, we can see the proposed devices' effective irradiance is less than secondary predicate's, so it means the proposed device will not raise safety concerns in this particular difference. (Because the main risk of light irradiation therapy is the heat energy converted by light irradiation. The greater the light irradiation, the higher the temperature of the treatment site, and the greater the risk of the patient being burned).

But smaller effective irradiance may raise the effectiveness concerns, the proposed device may not achieve it's claimed indication for use. Considering that the final energy acting on the human body is the fluence/energy density (J/cm^2), and the fluence/energy density (J/cm^2) is the effective irradiance (mW/cm^2) multiplied by the treatment time, that is, the actual energy acting on the human body is the accumulation of effective irradiance (mW/cm^2) energy in the human body. Therefore, when considering the difference in effectiveness about effective irradiance (mW/cm^2), we should take the fluence/energy density (J/cm^2) acting on the human body. We also conducted comparison about fluence/energy density (J/cm^2) in table above and provided the difference in Analysis 6 below, according to the results of difference analysis 6 below, the proposed device has similar fluence/energy density (J/cm^2) with both primary and secondary predicate device.

Therefore, this difference will not affect safety and effectiveness of the proposed device

Analysis 5:

The proposed device is different in Number of LEDs in each panel from the primary device (K221083) and predicate device (K180900). However, the therapeutic effect and harm of the final light energy are determined by the light energy acting on human body, which are fluence/energy

density (J/cm^2).

So, no matter the number of light sources will not affect the effect and risk of the final treatment. Additionally, by complying with IEC 60601-1, the mechanical and heat performance of the proposed device is determined to be accepted.

Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 6:

The Max fluence /energy density is calculated based on the treatment time. The Max fluence /energy density is equal to the effective irradiance by the treatment time. The final energy density can be adjusted by recommending treatment times. From the comparison above, the proposed device has similar fluence/energy density (J/cm^2) with primary predicate device (K221083) at 20 minutes treatment time, and also has similar fluence/energy density (J/cm^2) with secondary predicate device at 3 minutes treatment time. And the minor differences are all within ±20% acceptable range.

Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Analysis 7:

The proposed device is different in Treatment time from the primary devices. Although our treatment time is adjustable from 1-30 minutes, but we recommend a treatment time of 20 minutes and 3 minutes for different output energy type (we have added this information in Chapter 1.5 of the manual).

Additionally, the standard of IEC 60601-2-57 classified continuous running LS equipment, and the test results showed that even under the maximum energy flux of 30 minutes, we still comply with IEC 60601-2-57 and IEC 60601-1.

Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Analysis 8:

The proposed device is different in Lamps working distance from the predicate device.

The Effective radiation refers to the effective light energy intensity on the irradiated surface (the skin surface), and the effective radiation of the proposed device is measured at a distance of 7cm from the light source.

Although the Lamps working distance of the proposed device is different from that of the predicate device, the effective radiation received by the two on the unit area of the irradiation surface is same (skin surface).

Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Analysis 9:

The proposed device is different in Standard from the predicate device (K180900). The proposed device is Prescription Use and operated by professional personnel, so it does not need to be tested by IEC 60601-1-11. Moreover, the proposed device does not contact with patients, so it does not

need to be tested according to ISO 10993-1. Therefore, this difference will not affect safety and effectiveness of the proposed device.

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K221083 and K180900).