March 13, 2025

Xemis Medical Technology (Shenzhen) Co., Ltd.
Yongfen Yang
RA Engineer
1101/1102/1201/1202, Unit 1, Building 2, Hongpeng Building,
Tiegang Community, Xixiang Street, Baoan
Shenzhen, Guangdong 518102
China

Re: K243993
Trade/Device Name: Photon Therapy Apparatus (BL-10)
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: December 26, 2024
Received: December 26, 2024

Dear Yongfen Yang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.03.13 18:24:57 -04'00'

for Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243993

Device Name
Photon Therapy Apparatus (BL-10)

Indications for Use *(Describe)*
Photon therapy apparatus use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.
The red light (633±8nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.
The blue light (417±8nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
The Yellow light (590±8nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.
The infrared light (830±8nm 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.

K243993 - 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025-02-26

1. Submitter's identifications

Name: Xemis Medical Technology (Shenzhen) Co., Ltd.
Address: 1101/1102/1201/1202, Unit 1, Building 2, Hongpeng Building, Tiegang Community, Xixiang Street, Baoan, Shenzhen, China
Contact person: Yang Yongfen
Title: RA Engineer
E-mail: yangyongfen@ximisihn.com
Tel: 86-755-23316735

2. Subject Device Information

Trade/Device Name	Photon Therapy Apparatus
Model	BL-10
Product Code	GEX
Classification Panel	General & Plastic Surgery
Regulatory Class	Class II
Regulation Number	21 CFR878.4810
Submission type	Traditional 510(K)

3. Predicate Device

Device name and model	K number	Manufacturer
LED Light Therapy Device	K222751	Xuzhou Kernel Medical Equipment Co., Ltd.
Phototherapy System	K190938	Shanghai Apolo Medical Technology Co., Ltd.
Oxylight	K200104	RAJA Trading Company, Inc.

4. Device Description

The photon therapy apparatus (BL-10) use 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 (633±8nm), in the blue light regions of the light spectrum (417±8nm), yellow light area (590±8nm) and infrared light region of light spectrum (835±8nm).

The photon therapy apparatus (BL-10) are equipped with six type of optional irradiators, each of which emits three different colors of light sources. The details of different irradiators are as follows:

Table 1 Specification of different irradiators

REF No.	Types of irradiator	Specification
LT01	RBY Irradiator	Red/Blue/Yellow light, 3 panels
LT02	RBY Irradiator	Red/Blue/Yellow light, 5 panels
LT03	IBY Irradiator	Infrared /Blue/Yellow light, 3 panels
LT04	IBY Irradiator	Infrared /Blue/Yellow light, 5 panels
LT05	IRY Irradiator	Infrared /Red/Yellow light, 3 panels
LT06	IRY Irradiator	Infrared /Red/Yellow light, 5 panels

5. Intended use & Indication for use

Photon therapy apparatus use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.

The red light (633±8nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.

The blue light (417±8nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

The Yellow light (590±8nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.

The infrared light (830±8nm 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.

6. Summary of Substantial Equivalence

Table 2 Comparison to Predicate Device

	Proposed Device	**Predicate device**	**Predicate device**	**Predicate device**
510k Number	/	K222751	K190938	K200104
Product Code	GEX	GEX	GEX	GEX
Proprietary Name	Photon Therapy Apparatus	LED Light Therapy Device	Phototherapy System	Oxylight
Model	BL-10	KN-7000L	HS-770	/
Manufacturer	Xemis Medical Technology	Xuzhou Kernel Medical	Shanghai Apolo Medical	RAJA Trading Company, Inc.

	Proposed Device	**Predicate device**	**Predicate device**	**Predicate device**
	(Shenzhen) Co., Ltd.	Equipment Co., Ltd.	Technology Co., Ltd.	
Indications for Use	Photon Therapy Apparatus use of the red, blue, yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light (633±8nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light (417±8nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The yellow light (590±8nm wavelength) is	LED Light Therapy Device use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light (417±10 nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The Yellow light (590±10nm wavelength) is generally	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	The Oxylight is intended for dermatological use by physicians and healthcare professionals for the following: LED Technology is intended for: -Blue LED – 465nm – to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. -Red LED 625nm- for treatment of superficial, benign vascular and pigmented lesions. -Yellow LED 590nm - treatment of periorbital wrinkles and rhytides.

	Proposed Device	**Predicate device**	**Predicate device**	**Predicate device**
	generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides. The infrared light (830±8nm 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.	indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides. The infrared light (835±15nm 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.	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.	
Wavelength(s)(nm)	Red light 633±8nm Blue light 417±8nm Yellow light 590±8nm	Red light 633 ± 10nm Blue light 417±10nm Yellow light 590±10mm	Red light 630 ± 15nm Blue light 415 ± 15nm Infrared 835 ± 15nm	Red light 625nm Blue light 465nm Yellow light 590nm

	Proposed Device	**Predicate device**	**Predicate device**	**Predicate device**
	Infrared 830±8nm	Infrared 835 ± 15nm		
Panels Type	3 panel and 5 panel. The panels may emit the three light (red/yellow/blue, or infrared /yellow/blue, or infrared /yellow/red) individual or in combination	5 Panels The panels may emit the three light (red/blue/infrared, or red/blue/yellow) individual or in combination	3 panel and 4 Panel The panels may emit the three light (red, blue, infrared) individual or in combination	Three type, each head type has only one light. Red, Blue, yellow.
Output Power	Each panel has three different kinds of light-emitting diodes, and the energy power of the diode is as follows: Red light: 1.5~1.8W Yellow light: 1.5~1.8W Blue light: 2.2~2.5W Infrared: 1.1~1.4W	Each panel has three different kinds of light-emitting diodes, and the energy power of the diode is 0.5W	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 （mW/CM²）	(1)Red: 80mW/cm² (2)Blue: 100mW/cm2 (3)Yellow 35W/cm2	Red light: 20～96 mw/cm ² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ²	(1)Red light: 115mW/cm², (2)Blue light: 120mW/cm², (3)IR: 70mW/cm², (4)Red/IR:	(1)Red: 100mW/cm² (2)Blue: 45mW/cm2 (3)Yellow 35W/cm2

	Proposed Device	**Predicate device**	**Predicate device**	**Predicate device**
	(4)Infrared: 50mW/cm²	Infrared: ≤ 70 mw/cm ²	120mW/cm², (5)Blue/IR: 150mW/cm²	
Standard does in Joules	(1)Red: 96J/cm² (2)Blue: 120J/cm² (3)Yellow: 42J/cm² (4)Infrared: 60J/cm²	Red light: 155J/cm2, Blue light: 144J/cm2, Yellow light: 42J/cm2, IR: 84J/cm2	(1)Red light: 138J/cm², (2)blue light: 144J/cm², (3)IR: 84J/cm², (4)Red/IR: 144J/cm² (5)Blue/IR: 180J/cm²	(1)Red: 120J/cm² (2)Blue: 54J/cm² (3)Yellow: 42J/cm²
Adjustable dose range	(1) Red light: 1-144J/cm² (2) Blue light: 1-180J/cm² (3) Yellow light: 1-63J/cm² (4) Infrared: 3-90J/cm²	Red light: 20～96 J/cm² Blue light: 10～120J/cm² Yellow light: 5～35 J/cm² Infrared: ≤ 70 J/cm² Red/IR: 20～166 J/cm² Blue/IR: 10 ～ 190 J/cm²	(1)Red light: 1-242J/cm², (2)blue light:1-180J/cm², (3)IR:1-147J/cm², (4)Red/IR: 1-144J/cm², (5)Blue/IR:1-180J/cm²	(1)Red light: 1-240J/cm2, (2)blue light: 1-108J/cm2, (3)Yellow IR:1-84J/cm2
Effective irradiation area:（CM²）	825cm² and 1375cm²	900 cm² ±10%	756cm² and 1008cm²	500cm² and 860cm²
Structural style	Wheeled	Wheeled	Wheeled	Wheeled
Structure composition	Main frame, irradiator, support arm	Main frame, irradiator, lifting frame	Main frame, irradiator, lifting frame	Irradiator and support
Power supply	AC 100-240V 50/60Hz	AC 100-240V 50/60Hz	AC 100-240V 50/60Hz	AC 100-240V 50/60Hz
Treatment time	20min (Recommended treatment time)	20min (Recommended treatment time)	20min (Recommended treatment time)	20min (Recommended treatment time)

	Proposed Device	**Predicate device**	**Predicate device**	**Predicate device**
Operation interface	Display Screen	Display Screen	Display Screen	Display Screen
Software	Yes	Yes	Yes	Yes
Safety classification	Class I	Class I	Class I	Class I
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 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471

Substantial Equivalence discussion:

The indications for use of the Photon Therapy Apparatus are the same as those for the predicate devices. Most technical specifications of the Photon Therapy Apparatus are either the same or substantially equivalent as compared to the predicate devices. There are no significant technological differences that raise new or different questions of safety or effectiveness.

7. Non-clinical tests

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety, electromagnetic compatibility (EMC) and performance

Electrical safety, EMC and performance testing were performed to, and passed, the following standards:

- ANSI AAMI ES60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- 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 compatibility Requirements and tests
- IEC 60601-2-57: 2023 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 cosmetic and aesthetic use
- IEC 62471: 2006 Photobiological safety of lamps and lamp systems

Software Verification and Validation

Software documentation consistent with Basic Documentation Level of concern was submitted in this 510(k). System verification testing presented in this 510(k) demonstrated that all software requirement specifications are met.

8. Clinical study

Not applicable.

9. Conclusion

Based on comparing to predicate devices, the proposed device of BL-10 are determined to be Substantially Equivalent (SE) to the predicate devices, in respect of safety and effectiveness.