October 1, 2025

Shenzhen Ulike Smart Electronics Co.,Ltd.
Blue Yang
Registration Director
810, Building 1, Xunmei Science and Technology Plaza
No. 8 Keyuan Rd, Science Park Community, Yuehai Sub-District
Shenzhen,
China

Re: K251825
Trade/Device Name: Jmoon FlexGlow Light Therapy Device (JD20U SP, JD20U SG)
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: OHS, OLP
Dated: June 13, 2025
Received: September 2, 2025

Dear Blue 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.10.01 15:06:03 -04'00'

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)*
K251825

Device Name
Jmoon FlexGlow Light Therapy Device (JD20U SP, JD20U SG)

Indications for Use *(Describe)*
Jmoon FlexGlow Light Therapy Device is an over the counter device that is intended:
- the Red light and Infrared light is indicated for use in the treatment of full face wrinkles,
- the Blue light and Red light indicated for the treatment of mild to moderate inflammatory acne.

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.

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510(k) Summary of K251825

I. Submitter

Shenzhen Ulike Smart Electronics Co.,Ltd.
Address: 810, Building 1, Xunmei Science and Technology Plaza, No. 8 Keyuan Road, Science Park Community, Yuehai Sub-District, Nanshan District, Shenzhen 518000, Guangdong, P.R. China
Contact person: Blue Yang
Email: blue@ulike.com
The date the summary was prepared：6/15/2025

II. Device

Name of Device: Jmoon FlexGlow Light Therapy Device
Model(s): JD20U SP, JD20U SG
Common or Usual Name: Light based over the counter wrinkle reduction, Over-The-Counter Powered Light Based Laser For Acne
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810

III. Legally Marketed Predicate Devices

Legally Marketed Predicate Devices	Predicate Device 1		Predicate Device 2	Predicate Device 3
510(k) number	K223919		K210948	K240089
Trade Name	BEMER Light Therapy System Applicator: B. Light Clear Evo	BEMER Light Therapy System Applicator: B.Light Restore Evo	Omnilux CLEAR™	Face Patches
Manufacturer	BEMER Int. AG		Globalmed Technologies	Shenzhen Kaiyan Medical Equipment Co., Ltd
Device classification	Class II		Class II	Class II

IV. Device Description

Jmoon FlexGlow Light Therapy Device is an exclusive mirrored tabletop device that contains 464 LEDs. It utilizes LED(light-emitting diode) technology to emit energy in the blue, red and near-infrared spectra for the aim to improve the skin appearance, helping to reduce wrinkles, like fine lines and crow's feet, and treat mild to moderate inflammatory acne. The specific wavelengths

of light can act on different skin layers to produce different photobiological effects. The device is to be used at 1 cm distance.The flexible and foldable device unit is designed to be placed on a table for easy exposure to the face and body to ensure consistent light treatment. There are three modes: Acne defense Mode(M01), Anti-wrinkle recovery Mode(M02) and Dual care Mode(M03).

V. Indications for Use

Jmoon FlexGlow Light Therapy Device is an over the counter device that is intended:

- the Red light and Infrared light is indicated for use in the treatment of full face wrinkles,
- the Blue light and Red light is indicated for the treatment of mild to moderate inflammatory acne.

VI. Comparison of Technological Characteristics with the Predicate Device

Jmoon FlexGlow Light Therapy Device has the same intended use and similar operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices for its intended use. Therefore, Jmoon FlexGlow Light Therapy Device may be found substantially equivalent to its predicate devices.

Jmoon FlexGlow Light Therapy Device is compared with the following Predicate Devices in

Comparison Items	Subject Device	Predicate Device 1		Predicate Device 2	Predicate Device 3	Remark
510(k) number	/	K223919		K210948	K240089	/
Trade Name	Jmoon FlexGlow Light Therapy Device	BEMER Light Therapy System Applicator: B. Light Clear Evo	BEMER Light Therapy System Applicator: B.Light Restore Evo	Omnilux CLEAR™	Face Patches	/
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	BEMER Int. AG		Globalmed Technologies	Shenzhen Kaiyan Medical Equipment Co., Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810		21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHS, OLP	OLP	OHS	OLP	OHS, OLP, GEX	Same
Device classification	Class II	Class II		Class II	Class II	Same
Indications for use/ Intended	Jmoon FlexGlow Light Therapy Device	The device is intended for over-the-counter	Use of light based treatment to reduce wrinkles on	The Omnilux CLEAR acne facemask is	Face Patches (Model: MT-12MA)is an	Note 1

use	is an over the counter device that is intended: - the Red light and Infrared light is indicated for use in the treatment of full face wrinkles, - the Blue light and Red light is indicated for the treatment of mild to moderate inflammatory acne.	(OTC) use to treat patients with mild to moderate acne vulgaris on the face.	the face.	an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris on the face.	Over-the Counter(OTC) device intended for treatment of mild to moderate inflammatory acne. Face Patches (Model:MT-12 MC) is an Over-the Counter (OTC) device intended for treatment of mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles)	
Rx or OTC	OTC	OTC		OTC	OTC	Same
Location for use	Face and body	Face		Face	Face	Note 2
Power supply	Main unit:24V D.C.,1.5A Adapter Input:100-240V A.C., 50/60Hz, 1.3A Adapter Output:24V D.C., 1.5A	Control unit : Input voltage 100 -240 V AC / 50 - 60 Hz, 15 VDC / 2A Applicator: 15 V AC		unknown	Controller:3.6V, 65mAh lithium battery,0.234Wh	Note 3
Light source	LED	LED		LED	LED	Same
Wavelength	Red light: 630nm±10nm NIR light: 830nm±10nm Blue light: 415nm±10nm	Red: 645 nm ± 20 nm Blue: 465 nm ± 20 nm	IR: 860 nm ± 20 nm Red: 645 nm ± 20 nm	Red: 630nm +/- 5nm. Blue: 412.5nm +/- 7.5nm	For MT-12MA: 630+415nm For MT-12MC: 630nm(type1)+415nm; 830nm+630nm(t	Note 4

	M01： 415nm±10nm, 630nm±10nm M02： 630nm±10nm, 830nm±10nm M03: 415nm±10nm, 630nm±10nm, 830nm±10nm				ype2); 590nm	
Irradiance	M01: Blue:11.2 mW/cm² Red: 8.2 mW/cm² M02: IR: 7 mW/cm² Red: 8.1 mW/cm² M03:	Red: 0.76 mW/cm² Blue: 1.20 mW/ cm²	Red: 0.56 mW/cm² IR: 1.40 mW/cm²	Blue:28 mw/cm² Red:16 mw/cm² Total:44mw/cm²	For MT-12MA: 630nm:5 415nm:25 630+415nm:30 For MT-12MC: 630nm(type1):5 415nm:25 Mode1-total:30 830nm:15 630nm(type2):20 Mode2-total:35 Mode3-590nm:35	Note 5
Treatment Time	M01(5min)+ MI02 (5min) M01: 5min M02: 5min M03: 10 min (M01(5min)+ MI02 (5min))	8 min per day	8 min per day	10 Min	For MT-12MA (630+415nm): 3 minutes per treatment For MT-12MC (mode1 630+415nm):3 minutes per treatment For MT-12MC (mode2 630+830nm):9 minutes per treatment For MT-12MC (mode 3-590nm): 21 minutes per	Note 5

					treatment	
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Same
Eye safety	IEC 62471	IEC 62471		IEC 62471	unknown	Same

Note 1:
The acne removal function of Mode 1 of the subject device is consistent with predicate device 1. Mode 3 of the subject device is a continuous bonding of Mode 1 and Mode 2 so it has the functions of acne removal and wrinkle removal.

Note 2:
Though the applicable location is different from the predicate devices, the commonly recognized applicable location for LED device is mostly face or body. The applicable location of the subject device is face and body and usability evaluation has been conducted to verify them can use the device safely and effectively, so this difference will not raise any safety/ effectiveness problems.

Note 3:
Although the power supply of the subject device and predicate devices is not identical, the IEC 60601-1 test demonstrated the safety of the power adapter. The slight difference will not raise safety and effective issue.

Note 4:
The light wavelength is very similar. The wavelength of the subject device is similar to the predicate device 1. Besides, the subject device has passed IEC 62471, IEC60601-2-57 and IEC 60601-2-83 tests, so the slight difference will not raise safety and effective issue.

Note 5:
Although the “Irradiance” and “Treatment Time” are a little different from the predicate devices, the values of each treatment dose for these parameters are within the range of the predicate devices. Dose is equal to Irradiance * Time. Through calculation, it can be concluded that the dose of the subject device are within the range of the predicate devices.

Summary of performance testing
The following performance data were provided in support of the substantial equivalence determination.
1) Electrical Safety and EMC
Electrical safety and EMC testing was performed to, and passed, as per the following standards:
> IEC 60601- 1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
> IEC 60601- 1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral Standard:

Electromagnetic disturbances - Requirements and tests

> IEC 60601- 1- 11:2015+A1:2020 Medical Electrical Equipment– Part 1- 11: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

> IEC 60601-2-57:2011 Medical electrical equipment–Part 2-57: Particular requirements for the basic safety and essential performance of non-laser source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

> IEC 60601-2-83:2019+2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

2) Light Safety

> IEC 62471:2006 Photobiological safety of lamps and lamp systems

3) Software Verification and Validation

Software documentation consistent with ***Basic Documentation Level*** was submitted in this 510(k). System testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

4) Usability

The product usability has been evaluated and validated according to the following standard and FDA guidance.

> IEC 60601-1-6:2010+2013+2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

>Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016

Conclusion: Based on the comparison analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices.