January 10, 2025

Shenzhen Ulike Smart Electronics Co., Ltd.
Blue Yang
Registration Director
810, Building 1, Xunmei Science and Technology Plaza, No. 8
Science Park Community,Yuehai Sub-District, Nanshan District
Shenzhen, 518000
China

Re: K243492
Trade/Device Name: Ulike Reglow Light Therapy Device (UM10)
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: November 9, 2024
Received: November 12, 2024

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: 2025.01.10 12:43:42 -05'00'

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)*
K243492

Device Name
Ulike Reglow Light Therapy Device (UM10)

Indications for Use *(Describe)*
Ulike Reglow Light Therapy Device is an over the counter device that is intended for use in the treatment of full face wrinkles and 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.

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510(k) Summary #K243492

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：11/09/2024

II. Device

Name of Device: Ulike Reglow Light Therapy Device
Model(s): UM10
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. Device Description

Ulike Reglow Light Therapy Device adopts light emitting diodes (LED) in the 630nm±10nm,830nm±10nm,590nm±10nm and 465nm±10nm spectrum to irradiate on the face to realize its therapeutic effect. The Ulike Reglow Light Therapy Device adopts the form of a mask that contains LEDs on the inner surface of the main unit. A controller is connected to the main unit to control the device, such as turn on/off the device, switch mode. Power adapter is provided to charge the battery contained in the controller. To use the device, user should place the mask over the face and use the controller to operate. To prevent irradiation of LED lights to eyes during the treatment, Ulike Reglow Light Therapy Device has incorporated protective eye-shield which blocks light energy from LEDs.

IV.Indications for Use

Ulike Reglow Light Therapy Device is an Over the Counter device that is intended for the use in the treatment of full face wrinkles and treatment of mild to moderate inflammatory acne.

V. Comparison of Technological Characteristics With the Predicate Devices

The Ulike Reglow 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, the Ulike Reglow Light Therapy Device may be found substantially equivalent to its predicate devices.

Ulike Reglow Light Therapy Device is compared with the following Predicate Devices in terms of intended use, design, specifications and performance:

Comparison Items	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Remark
510(k) number	/	K133896	K223544	K240089	/
Trade Name	Ulike Reglow Light Therapy Device	RejuvaliteMD	LED light therapy mask	Face Patches	/
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	Trophy Skin Incorporated	Guangdong Newdermo Biotech Co.,Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	Same Note1
Product code	OHS,OLP	OHS	OHS,OLP,ILY	OHS, OLP, GEX	Same Note1
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	Ulike Reglow Light Therapy Device is an Over the Counter device that is intended for the use in the treatment of full face wrinkles and treatment of	The RejuvaliteMD is an Over the Counter device that is intended for the use in the treatment of full face wrinkles.	Red light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Infrared light: Provide	Face Patches (Model: MT-12MA)is an Over-the Counter(OTC) device intended for treatment of mild tomoderate inflammatory acne. Face	Same Note1

	mild to moderate inflammatory acne.		topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. Mixed light: Treatment of mild to moderate inflammatory acne.	Patches (Model:MT-12MC) is an Over-the Counter (OTC) device intended for treatment of mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles)	
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Location for use	Face	Face	Face and body	Face	Same
Power supply	Controller:3.7V, 2600mAh lithium battery, 9.62Wh	AC to DC	Input: 100-240 V~, 50/60 Hz, 0,25 A Output: DC 5 V, 500 mA	Controller:3.6V, 65mAh lithium battery,0.234Wh	Note 2
Light source	LED	LED	LED	LED	Same
Wavelength	465nm, 590nm, 630nm, 830nm	600,622,660,860nm	Red: 620nm Blue: 460nm Infrared: 850nm	MT-12MA: 630±10nm 415±10nm MT-12MC:415nm	Note 3

			Mixed: 620nm and 850nm and 460nm	±10nm,630nm± 10nm,830nm± 10nm,590nm± 10nm	
LED Intensity	1-40mW/cm2	62 mW/cm2 at a distance of 4” from the LED head	Red light: 2.0~3.0 mW/cm2 Blue light:2.0~4.0 mW/cm2 Infrared light: 2.0~4.0 mW/cm2 Mixed light: 9.0~12.0 mW/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 4
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 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Same
Eye safety	IEC 62471	IEC 62471	unknown	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

Note 1:
Although the Regulation number and Product code of predicates are not identical to the subject device, all these device are process similar intended use and use very similar light wavelengths to get the intended purpose. This slight deference will not raise safety and effective issue.

Note2:
The power supply of subject device is similar to predicate 3 and the IEC 62133-2 test demonstrated the safety of the lithium battery. The slight difference will not raise safety and effective issue.

Note 3
The light wavelength is very similar. The subject device emits blue light, red light and IR light simultaneously, while the predicate device 1 can emit red, blue, IR light simultaneously and it has been demonstrated that emit those lights simultaneously is safe and effect. 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 4
Although the LED Intensity of these devices are different, the LED intensity of the subject device is within the range of predicate devices. Moreover, 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.

Summary of performance testing

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

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Ulike Reglow Light Therapy Device was conducted in accordance with the "Use of International Standard ISO 10993- 1, 'Biological Evaluation of Medical Devices–Part 1: Evaluation and Testing Within a Risk Management Process, Document", as recognized by FDA. The following testing was performed to, and passed, including:

> ISO 10993-10:2021, Biological evaluation of medical devices Part 10: Tests for skin sensitization

> ISO 10993-23:2021, Biological evaluation of medical devices Part 23: Tests for irritation

> ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

2) 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 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

> IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolvtes - Safety reguirements for portablesealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

3) Light Safety

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

4) 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.

5) Usability

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

> IEC 60601-1-6 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 above analysis and non-clinical tests performed, it can be concluded that the subject device Ulike Reglow Light Therapy Device is as safe, as effective, and performs as well as the legally marketed predicate devices.