March 16, 2026

Shenzhen Ulike Smart Electronics Co., Ltd.
Blue Yang
Registration Director
810, Bldg. 1, Xunmei Science And Technology Plaza, # 8 Keyuan Rd., Science Park Community,
Yuehai Sub-District, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K260511
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: February 13, 2026
Received: February 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.03.16 18:40:24 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260511

Please provide the device trade name(s).

Ulike Reglow Light Therapy Device (UM10)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

510(k) Summary of K260511

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：03/06/2026

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 272 light emitting diodes (LED) with the multi-wavelength of 630nm±10nm,830nm±10nm,590nm±10nm and 465nm±10nm spectrum to irradiate the facial area to realize its therapeutic effect, including reducing wrinkles and treating mild to moderate inflammatory acne, which improves overall skin appearance.
The Ulike Reglow Light Therapy Device adopts the form of a mask that contains LEDs on the inner surface of the main unit. The device is with user-friendly operation through a controller which is connected to the main unit to control the device, such as turn on/off the device, switch mode.
The device offers four selectable operating modes via the external controller:

- Mode 1 (Glow mode): 630 nm + 830 nm + 590 nm
- Mode 2 (Anti-Aging mode): 630 nm + 830 nm
- Mode 3 (Restoring mode): 590 nm + 830 nm
- Mode 4 (Clear mode): 465 nm + 630 nm + 830 nm

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. Technological comparison with the Predicate Device

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

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

Comparison Items	Subject Device	Predicate Device 1	Remark
510(k) number	/	K243492	/
Trade Name	Ulike Reglow Light Therapy Device	Ulike Reglow Light Therapy Device	/
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co., Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHS,OLP	OHS,OLP	Same
Device classification	Class II	Class II	Same
Indications 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 mild to moderate inflammatory acne.	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.	Same
Prescription or OTC	OTC	OTC	Same
Location for use	Face	Face	Same
Power supply	Controller:3.7V, 2600mAh lithium battery, 9.62Wh	Controller:3.7V, 2600mAh lithium battery, 9.62Wh	Same
Light source	LED	LED	Same
Wavelength	Mode 1: 630nm+ 830nm+590nm Mode 2: 630nm+830nm Mode 3: 590nm+ 830nm Mode 4: 465nm+	Mode 1: 630nm+ 830nm+590nm Mode 2: 630nm+830nm Mode 3: 590nm+ 830nm Mode 4: 465nm+	Same

	630nm+830nm	630nm+830nm	
LED Intensity	1-40mW/cm2	1-40mW/cm2	Same
Treatment Time	Mode 1:5 minutes each time Mode 2:8 minutes each time Mode 3:8 minutes each time Mode 4:5 minutes each time	Mode 1:5 minutes each time Mode 2:8 minutes each time Mode 3:8 minutes each time Mode 4:5 minutes each time	Same
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	Same
Eye safety	IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same
Modifications	1.Add component suppliers Add a battery supplier with the same specifications Add LEDs supplier with the same specifications 2. Add a kind of package contents：not providing adaper, only providing Type C charging Orignal version:Reglow Light Therapy Device*1+Rechargeable Remote*1+User Manual*1+Adapter*1 Added version:Reglow Light Therapy Device*1+Rechargeable Remote*1+User Manual*1+Type-C charging cable*1	/	Substa nially equival ent

Summary of performance testing

1. IEC 62133-2:2017+2021, 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
2. IEC 62471:2006 Photobiological safety of lamps and lamp systems
3. Wavelength and Irradiance Performance Test Report
4. IEC 60601- 1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance，relevant clauses
5. 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，relevant clauses
6. 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，relevant clauses

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 device.