May 1, 2025

Shenzhen Qianyu Technology Co., Ltd.
℅ Riley Chen
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, 518052 Cn

Re: K244020
Trade/Device Name: Wrinkle Treatment Device (JM1, JM2B)
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
Dated: December 27, 2024
Received: April 2, 2025

Dear Riley Chen:

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: 2025.05.01 19:44:48 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K244020

Device Name
Wrinkle Treatment Device (JM1, JM2B)

Indications for Use *(Describe)*
The Wrinkle Treatment Device is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles.

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: K244020

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

Shenzhen Qianyu Technology Co., Ltd.

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Preparation Date: May 1, 2025

II. Device

Name of Device: Wrinkle Treatment Device

Model(s): JM1, JM2B

Common or Usual Name: Light Based Over the Counter Wrinkle Reduction

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

Regulatory Class: II

Product Code: OHS

Regulation Number: 21 CFR 878.4810

III. Predicate Device

Manufacture	Trade Name	510(k) Numbe	Cleared Date
Shenzhen Qianyu Technology Co., Ltd.	Wrinkle Treatment Device (JM2)	K240360	April 5, 2024

IV. Device Description

The Wrinkle Treatment Device is an Over-the-Counter (OTC), home-use, wearable light based device, and intended for the use in treating full-face wrinkles. Light radiates from the inner surface of the device onto the face. This light is generated by VCSEL (Vertical-cavity surface-emitting laser) with two different spectrum wavelengths: red (660nm) and infrared (850nm).

Model JM1 is controlled directly by the button on the main mask body, which can realize device's power on/off and mode switch. The device will automatically shut down when the treatment time is over or when the pure water is run out.

Model JM2B is controlled by a controller that is connect to the main unit and the device's power-on/off, mode switch and treatment time adjustment can be operated by the controller. The device will automatically shut down when the treatment time is over.

Both models are powered by rechargeable Li-battery.

V. Indications for Use

The Wrinkle Treatment Device is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles.

VI. Comparison of Technological Characteristics With the Predicate Device

The Wrinkle Treatment Device has the same intended use as the predicate device. The technological characteristics such as wavelength, intensity, are similar to 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 as safe and as effective as the predicate device for its intended use.
Therefore, the Wrinkle Treatment Device may be found substantially equivalent to its predicate device.

Items	Subject device	Predicate device	Difference discussion
K number	Pending	K240360	/
Device trade name	Wrinkle Treatment Device, Model: JM1, JM2B	Wrinkle Treatment Device, Model: JM2	/
Device Class	Class II	Class II	Same
Intended use	The Wrinkle Treatment Device is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles.	The Wrinkle Treatment Device is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles.	Same
Prescription/ OTC	OTC	OTC	Same
Shape design	Mask	Mask	Same
No. of Light Sources	JM1: 136 JM2B: 140	140	Comparable
Fluence	JM1: 90/100 $mWcm^2$ JM2B: 40/70/100 $mWcm^2$	40/70/100 $mWcm^2$	Comparable
Treatment size	JM1: 260cm^2 JM2B: 330cm^2	330cm^2	Comparable
Intended location of use	Entire face	Entire face	Same
Energy type	VCSEL	LED	Different
Wavelength	660, 850nm (±20nm)	660, 850nm ±20nm	Same
Power supply	Rechargeable Li-ion battery	Rechargeable Li-ion battery	Same
Main materials	JM1: Silica gel, PVC, ABS, PC JM2B: Silica gel, PVC, ABS	Silica gel, PVC, ABS	JM1: Different JM2B: Same

VII. Performance Data

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

1) Biocompatibility Evaluation

This evaluation was not needed for JM2B since material of the subject device (JM2B) and predicate devices is identical in composition and processing.

The biocompatibility evaluation for the JM1 of Wrinkle Treatment 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 Issued on September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

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

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per 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 compatibility
- IEC 60601-1-11:2020, Medical Electrical Equipment –Part 1: 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 60825-1: 2014, Safety of laser products - Part 1: Equipment classification, and requirements

3) Thermal Performance Evaluation

- Bench testing was performed to evaluate the fluence contribution of each wavelength.
- Bench testing was performed to demonstrate the magnitude and distribution of the fluence that could be delivered to the face for each wavelength.
- Thermal performance evaluation was performed in ex vivo tissue to demonstrate the spatio-temporal temperature distribution and thermal accumulation.

4) Software Verification and Validation

Software documentation consistent with ***Basic Documentation level*** of concern was submitted in this 510(k). System validation 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 verified according to the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices", issued on FEBRUARY 2016.

VIII. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Wrinkle Treatment Device is as safe and as effective as the legally marketed predicate device.