April 5, 2024

Shenzhen Qianyu Technology Co., Ltd.
Guoyang Li
Certification Engineer
Room 601, Han's Technology Center. No.9988, Shennan Avenue
Maling Community,Yuehai Street, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K240360
Trade/Device Name: Wrinkle Treatment Device (JM2)
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: February 3, 2024
Received: February 6, 2024

Dear Guoyang Li:

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.

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
Tanisha L. Hithe -S
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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.

Submission Number *(if known)*

K240360

Device Name

Wrinkle Treatment Device (JM2)

Indications for Use *(Describe)*

The wrinkle treatment device (model: JM2) 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

Prepared on: 2024-04-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Qianyu Technology Co., Ltd.
Applicant Address	Room 601, Han's Technology Center. No.9988, Shennan Avenue, Maling Community,Yuehai Street, Nanshan District Shenzhen Guangdong 518000 China
Applicant Contact Telephone	+86 15099998872
Applicant Contact	Mr. Guoyang Li
Applicant Contact Email	liguoyang@jovs-beauty.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Wrinkle Treatment Device (JM2)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Light Based Over The Counter Wrinkle Reduction
Regulation Number	878.4810
Product Code(s)	OHS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230293	TheraFace Mask	OHS
K210954	Synergy	OHS
K162489	RED Light Device	OHS

Device Description Summary

21 CFR 807.92(a)(4)

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 LED with two different spectrum wavelengths: red (660nm) and infrared (850nm).
The device is powered by rechargeable Li-battery and controlled by a controller that is connect to the main unit. 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The wrinkle treatment device (model: JM2) is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device and predicate devices (K230293, K210954) have the same indications for use, they are all over-the-counter device and

intended for the use in treating full face wrinkles.

Technological Comparison

21 CFR 807.92(a)(6)

The technical characteristics of Winkle Treatment Device (JM2) are substantially equivalent to the predicate devices in the following aspects:
1. the same shape design as the primary predicate device (K230293): they are all mask design.
2. the same intended location of use: they are all for the entire face.
3. the same energy source: they all use rechargeable Li-ion battery.
4. the same energy type: LED
5. similar wavelength: the wavelength of subject device (660, 850nm ±20nm) is a little different from the primary predicate device (Red: 633 ±10nm, Blue: 415 ±10nm, Red+IR: 633nm±10nm/ 830±10nm), but the wavelength of the subject device is equivalent to the secondary predicate device (610, 630, 660, 850nm ±5nm), and the device complies with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.
6. similar intensity: the intensity of the subject device is a slightly different from the predicate devices, it is within the maximum range of the reference device (K162489), and the subject device complies with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

The difference between the subject device and the predicate devices mainly includes the following:
1. different treatment size: the treatment size of subject device (330cm2) is different from the secondary predicate device, but the subject device is a mask design device that is the same as the primary predicate device, so this difference does not raise any new issues of safety or effectiveness.
2. different main materials: the subject device is composed of silica gel, PVS, ABS, which is different from the predicate devices, but it is solved by biocompatibility test.

Thus, the subject device is determined to be substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testings have been conducted to verify that the Winkle Treatment Device meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the subject device complies with 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 disturbances - Requirements and tests
IEC 60601-1-11:2020, 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 60601-2-83:2019, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
IEC 62471:2006, Photobiological safety of lamps and lamp systems
IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

The device has been tested for biocompatibility, it complies with the following standards.
ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation

We have also conducted:
Software verification and validation test according to the requirements of the FDA "Content of Premarket Submissions for Device Software Functions"

The clinical test is not applicable, there is no clinical data.

The subject device and predicate devices have the same indications for use, similar technological characteristics.
The subject device is as safe, as effective and performs as well as the predicate devices.