



January 30, 2024

Wuhan Lotuxs Technology Co., Ltd.
Na Wu, Quality Manager
501/E2, No.999 High-tech Avenue
Wuhan, Hubei 430206
China

Re: K231910

Trade/Device Name: DermRays Revive

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: GEX

Dated: December 13, 2023

Received: December 13, 2023

Dear Na Wu:

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
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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

Indications for Use

510(k) Number (if known)

K231910

Device Name

DermRays Revive (LHR-S5-1064)

Indications for Use (Describe)

DermRays Revive is intended for hair removal, permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

DermRays Revive is also intended for treatment of wrinkles.

DermRays Revive is intended for use on all skin types (Fitzpatrick skin types I - VI), including tanned skin.

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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**Section 5 - 510(k) Summary
K231910**

Date of Summary Preparation: June 25, 2023

Date of Summary Modification: January 09, 2024

1. Submitter's Identifications

Submitter's Name: Wuhan Lotuxs Technology Co., Ltd.

Address: 501/E2, No.999 High-tech Avenue, Wuhan 430206, China

Contact Person: Na Wu

Contact Title: Quality Manager

Contact Email Address: na.wu@lotuxs.com

Telephone: +86-27-87619668

2. Correspondent's Identifications

Correspondent's Name: Wuhan Lotuxs Technology Co., Ltd.

Address: 501/E2, No.999 High-tech Avenue, Wuhan 430206, China

ZIP Code: 430206

Contact Person: Na Wu

Contact Title: Quality Manager

Contact E-mail Address: na.wu@lotuxs.com

Telephone: +86-27-87619668

3. Name of the Device

Device Classification Name: Powered laser surgical instrument

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

Trade Name: DermRays Revive

Model: LHR-S5-1064

Classification Panel: General & Plastic Surgery

Product Code: GEX

Regulation Number: 21 CFR 878.4810

Device Classification: Class II

4. The Predicate Devices

Primary predicate device: K141425 Cynosure Elite+ Laser

Secondary predicate device: K232117 Diode Laser Hair Removal

5. Device Description

DermRays Revive uses a diode laser with an output wavelength of 1064nm, to act on the dermis through the epidermis, and the laser energy is absorbed by the target tissues (melanin, hemoglobin, and water).

Due to the selective photothermal effect of the laser, it can treat wrinkles, without damaging the skin. Simultaneously, the laser can act on the melanin in the hair follicles, destroy hair follicles in the growth around the hair follicles, so as to remove hairs.

The device consists of a power adapter, a power cord and a main unit.

6. Intended Use of Device

DermRays Revive is intended for hair removal, permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

DermRays Revive is also intended for treatment of wrinkles.

DermRays Revive is intended for use on all skin types (Fitzpatrick skin types I - VI), including tanned skin.

7. Summary of Substantial Equivalence

Table 1

	Proposed device	Primary predicate device	Secondary predicate device	Comparison
510k Number	K231910	K141425	K232117	——
Product Code	GEX	GEX	GEX	——
Proprietary Name	DermRays Revive	Cynosure Elite+ Laser	Diode Laser Hair Removal	——
Model	LHR-S5-1064	/	LHR-V6S-1064, LHR-V6S/B-1064	——
Manufacture	Wuhan Lotuxs Technology Co., Ltd.	Cynosure LLC	Wuhan Lotuxs Technology Co., Ltd.	——
Indications for use	DermRays Revive is intended for hair removal, permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. DermRays Revive is also intended for treatment of wrinkles. DermRays Revive is intended for use on all skin types (Fitzpatrick skin types I - VI), including tanned skin.	1064 nm: The Cynosure Elite+ Laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun	Diode Laser Hair Removal (LHR-V6S-1064, LHR-V6S/B-1064) is intended for hair removal, permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. Diode Laser Hair Removal (LHR-V6S-1064, LHR-V6S/B-1064) is intended for use on all skin types (Fitzpatrick skin types I - VI),	Same

		spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. Additionally, the laser is indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	including tanned skin.	
Laser Type	Solid state	Solid state	Solid state	Same
Wavelength	1064nm±10nm	1064nm±10nm	1064nm±10nm	Same
Treatment Activation	Fingerswitch	Fingerswitch	Fingerswitch	Same
Rx/OTC	Prescription	Prescription	Prescription	Same
Pulse Width	400ms	0.1ms-300ms	LHR-V6S-1064: 350ms-450ms LHR-V6S/B-1064: 280ms-400ms	Same ¹
Single Pulse Max. Energy Density	5.0J/cm ² -10.0J/cm ²	4.7J/ cm ² (under 24mm handpiece spot size) 12.0J/cm ² (under 15mm handpiece spot size)	LHR-V6S-1064: 5J/cm ² , 6 J /cm ² , 7J/cm ² LHR-V6S/B-1064: 4J/cm ² , 5J/cm ² , 6J/cm ²	Similar ²

Handpiece Spot Size	15mm	3mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm & 24mm	30mm×10mm	Same ³
Working Area	1.766cm ²	4.522cm ² (under 24mm handpiece spot size) 1.766cm ² (under 15mm handpiece spot size)	3cm ²	Same ³
Input Voltage	AC100-240V, 50/60Hz, 1.6A Max.	208/240VAC, 30A, 50/60Hz, Single Phase	AC100-240V, 50/60Hz, 1.6A Max.	Same ⁴

Note 1: Pulse Width of the proposed device is same as the secondary predicate device LHR-V6S/B-1064 of K232117.

Note 2: Maximum energy density of a single pulse of the proposed device is similar to those of the primary predicate device K141425 (1064nm) and secondary predicate device K232117. These slight differences do not affect to safety and effectiveness of the proposed device.

Note 3: Handpiece Spot Size and Working Area of the proposed device are same to those of the secondary predicate device K141425 (15mm, 1.766 cm²).

Note 4: Input Voltage of the proposed device is same as the secondary predicate device K232117.

Discussion for Substantially Equivalent (SE):

The proposed device DermRays Revive LHR-S5-1064 has the same indications for use, laser type, wavelength, treatment activation, prescription, pulse width, handpiece spot size and working area, input voltage; has similar single pulse max. energy density. These different items can be controlled within the scope of application. These slight differences between the proposed devices and predicate devices do not cause new safety and effectiveness problems. According to the non clinical test results and use evaluation report, the proposed device is as safe, effective and has good performance as the predicate device.

So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

8. Non-Clinical Tests Submitted

The following non-clinical testing was provided in this 510(k) submission:

Biocompatibility Testing

According to ISO 10993-1:2018, we performed biocompatibility test for the parts that may directly contact the intact skin of the patient or operator, including in vitro cytotoxicity test per ISO 10993-5:2009, skin sensitization test per ISO 10993-10:2021, irritation test per ISO 10993-23:2021.

Electrical Safety and Electromagnetic Compatibility Testing

The proposed device was tested and complied with the applicable requirements of the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-22 and IEC 60825-1, demonstrated that the basic safety and performance of the device met the requirements.

Software Verification and Validation

Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

9. Concise summary for performance testing

From the performance testing - bench, we have a brief summary as follow:

1. Performance Test: Appearance, Function, Safety, Label.
2. Shelf Life Test: Accelerated aging test, and performance test after accelerated aging test).
3. Cleaning and Disinfection Verification: Simulated cleaning and disinfection test, and performance test after simulated cleaning and disinfection test.

All the bench test results are provided in Performance Test Report.

10. Clinical Study

No clinical testing has been performed.

11. Conclusions

After analyzing both bench and external laboratory testing data, the intended use and supporting data can conclude that the device in the submission is substantially equivalent to the predicate device.