November 28, 2023

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

Re: K232117
Trade/Device Name: Diode Laser Hair Removal (LHR-V6S-1064, LHR-V6S/B-1064)
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: November 24, 2023
Received: November 24, 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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2023.11.28 09:42:19 -05'00'

For 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232117

Device Name

Diode Laser Hair Removal (LHR-V6S-1064, LHR-V6S/B-1064)

Indications for Use *(Describe)*

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), 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 4 - 510(k) Summary

Date of Summary Preparation: July 14, 2023
Date of Summary Modification: November 24, 2023

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: Diode Laser Hair Removal
Model: LHR-V6S-1064, LHR-V6S/B-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: K133319 ET LightSheer 1060 and High Speed LightSheer 1060
Secondary predicate device: K141425 Cynosure Elite+ Laser

5. Device Description

The Diode Laser Hair Removal device models LHR-V6S-1064 and LHR-V6S/B-1064 emit pulses of invisible infrared laser light of 1064nm wavelength that penetrates into the skin and is selectively absorbed by melanin in the hair follicles. This creates a localized thermal effect that disrupts hair growth from the hair follicles. The device contains a sensor that detects contact with the skin so that the device will only emit the infrared laser pulses when the sensor is in contact with the skin. The device also includes a skin cooling feature and the device is powered by an external AC/DC power adaptor.

6. Intended Use of Device

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), including tanned skin.

7. Summary of Substantial Equivalence

Table 1

	Proposed device	Primary predicate device	Secondary predicate device	Comparison
510k Number	K232117	K133319	K141425	——
Product Code	GEX	GEX	GEX	——
Proprietary Name	Diode Laser Hair Removal	ET LightSheer 1060 and High Speed LightSheer 1060	Cynosure Elite+ Laser	——
Model	LHR-V6S-1064, LHR-V6S/B-1064	/	/	——
Manufacture	Wuhan Lotuxs Technology Co., Ltd.	Lumenis Ltd.	Cynosure LLC	——
Indications for use	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)	ET LightSheer 1060 and High Speed LightSheer 1060 are intended for treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions. ET LightSheer 1060 and High Speed LightSheer 1060 are intended for hair removal, permanent hair reduction, and the treatment for	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, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars,	Same

	is intended for use on all skin types (Fitzpatrick skin types I - VI), including tanned skin.	Pseudofolliculitis Barbae (PFB3). 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. ET LightSheer 1060 and High Speed LightSheer 1060 are intended for the treatment of benign pigmented lesions, including age spots, solar lentigines, eaf6-au-lait spots, nevi of Otallto, melasma, Becker's nevi and other benign pigmented lesions. ET LightSheer 1060 and High Speed LightSheer 1060 are also intended for treatment of wrinkles. ET LightSheer 1060 and High Speed LightSheer 1060 are intended for use on all skin types (Fitzpatrick skin	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 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	

		types I - VI), including tanned skin.	regime.	
Laser Type	Solid state	Solid state	Solid state	Same
Wavelength	1064nm±10nm	1060nm	1064nm±10nm	Same
Treatment Activation	Fingerswitch	Footswitch or Fingerswitch	Footswitch or Fingerswitch	Same
Rx/OTC	Prescription	Prescription	Prescription	Same
Pulse Width	LHR-V6S-1064: 350ms-450ms LHR-V6S/B-1064: 280ms-400ms	ET LightSheer 1060 handpiece: 5-400ms High Speed LightSheer 1060 handpiece: 30-400ms	0.1ms-300ms	Similar[1]
Repetition Rate	5Hz	ET LightSheer 1060 handpiece: Up to 3Hz High Speed LightSheer 1060 handpiece: Up to 3Hz	1-10Hz	Similar[1]
Maximum energy density of a single pulse	LHR-V6S-1064: 5J/cm², 6 J /cm², 7J/cm² LHR-V6S/B-1064: 4J/cm², 5J/cm², 6J/cm²	ET LightSheer 1060 handpiece: 10-100 J/cm² High Speed LightSheer 1060 handpiece: 4.5-14 J/cm²	14.0J/cm^2 (under 20mm handpiece spot size)	Similar[2]
Handpiece Spot Size	30mm×10mm	ET LightSheer 1060 handpiece: 9mm×9mm High Speed LightSheer 1060 handpiece: 22 mm×35mm	3mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm & 24mm	Similar[3]
Working Area	3cm^2	ET LightSheer 1060 handpiece: 0.81cm^2 High Speed LightSheer 1060 handpiece: 7.7cm^2	3.14cm^2 (under 20mm handpiece spot size)	Similar[3]
Input Voltage	AC100-240V, 50/60Hz, 1.6A Max.	AC100-240V, 50/60Hz, 10A, Single Phase	208/240VAC, 30A, 50/60Hz, Single Phase	Similar[4]

Note 1: Pulse Width and Repetition Rate of the proposed device are similar to those of the primary predicate device K133319 and secondary predicate device K141425.

These slight differences do not affect to safety and effectiveness of the proposed device.

Note 2: Maximum energy density of a single pulse of the proposed device is similar to those of the primary predicate device K133319. These slight differences do not affect to safety and effectiveness of the proposed device.

Note 3: Handpiece Spot Size of the proposed device is similar to that of High Speed LightSheer 1060 handpiece of the primary predicate device K133319. Working Area of the proposed device is similar to that of the secondary predicate device K141425. These slight differences do not affect to safety and effectiveness of the proposed device.

Note 4: Input Voltage of the proposed device is similar to those of the primary predicate device K133319 and the secondary predicate device K141425. These slight differences do not affect to safety and effectiveness of the proposed device.

Discussion for Substantially Equivalent (SE):
The proposed device Diode Laser Hair Removal LHR-V6S-1064, LHR-V6S/B-1064 has the same indications for use, laser type, wavelength, treatment activation, prescription, handpiece spot size, working area. The difference exists in such contents: pulse width, repetition rate, maximum energy density of a single pulse, input voltage. These 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 on safety and effectiveness in the proposed indication of hair removal, 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 propoesd 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
The summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device. 807.92(b)(3)