June 2, 2022

Leaseir Technologies S.L.U.
℅ Vardhini Kirthivas
Vice President – Quality & Regulatory Affairs
Freyr Global Regulatory Solutions and Services
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Gachibowli, Hyderabad, Telangana 500081
India

Re: K214049
Trade/Device Name: Leaseir MHR Xcell
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: April 28, 2022
Received: May 3, 2022

Dear Vardhini Kirthivas:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya, D.Eng.
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.

510(k) Number *(if known)*
K214049

Device Name
Leaseir MHR Xcell

Indications for Use *(Describe)*
Indications for use for Leaseir MHR Xcell diode laser hair removal system with 810nm applicator includes:
• Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.
• Treatment of Pseudofolliculitis barbae (PFB)
• Use on all skin types (Fitzpatrick I-VI)

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 (K214049)

1. Submitter Information:

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Date Prepared: 01-June-2022

2. Device Identification:

Device Trade Name: Leaseir MHR Xcell
Common Name: Powered Laser Surgical Instrument
Classification Name: Powered Laser Surgical Instrument

Table 1 Device Identification

Regulation No.	Product Code	Device Class
21 CFR 878.4810	GEX	Class II

3. Predicate Device

ELYSION-PRO by High Technology Products SLU with the K-Number K193367

4. Device Description

The Leaseir MHR Xcell is a surgical laser instrument for use in general and plastic surgery and dermatology, intended for hair removal and treatment of pseudo folliculitis barbae on all skin types (Fitzpatrick I-VI).

The process implies the generation of intense light pulses at specific wavelengths. The specific nature of the energies and pulse durations cause the desired effect (in the hair follicles and oxyhemoglobin in the blood) heating them sufficiently and destroying them without unnecessary damage to surrounding tissue. This is achieved by controlled emission of laser radiation to the target tissue.

The system consists of a main console and two interchangeable applicators that delivers pulsed light in the range of 800-820nm with a peak in the 810nm in different spot sizes. Two of the applicators emitting radiation at 810 nm wavelength for two areas 13.5×15 mm² and 14.5×25.5 mm². Two different operation modes are available: static mode and dynamic mode, which are differentiated basically by the frequency range defined for each mode (1-4 Hz for static and 10 Hz for dynamic).

The principle of operation consists in the photons travel along the axis and reflected again back into the crystal, continuing the chain reaction, while photons travelling in different directions leave the crystal. In one of the two mirrors, a tiny hole allows a small amount of light to leak out and the resulting beam is focused with lenses and is emitted from the laser. The total energy emitted by the Leaseir MHR Xcell is produced by an array of diodes.

The laser emission is activated by the hand piece trigger, deliver a continuous pulse pattern while the button is pressed.

5. Intended Use and Indications for Use

Indications for use for Leaseir MHR Xcell diode laser hair removal system with 810nm applicator includes:

- Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.
- Treatment of Pseudofolliculitis barbae (PFB)
- Use on all skin types (Fitzpatrick I-VI)

6. Comparison of Technological Characteristics with Predicate Device

The following table is used to compare the technological characteristics of the subject device, Leaseir MHR Xcell with those of the predicate device, Elysion-Pro.

Table 2 Summary of the comparison of Technological Characteristics

Parameters for Substantial Equivalence	**Subject Device** **Leaseir MHR Xcell**	**Predicate Device** **Elysion-Pro**	**Remarks**
510(k) Number	**N/A**	**K193367**	
Manufacturer	Leaseir Technologies	High Technology Products SLU	N/A
Product code	GEX	GEX	SE
Regulation number	878.4810	878.4810	SE
Panel	General & Plastic Surgery	General & Plastic Surgery	SE
Class	II	II	SE
Principle of Operation	AlGaAs laser diode stack	AlGaAs laser diode array	SE
Laser contact	Pure sapphire, Al_2O_3	Pure sapphire, Al_2O_3	SE
Laser wavelength	Dual 810b: 810nm Quad 810b:810nm	755nm, 810 nm	SE
Laser classification	Class IV	Class IV	SE
Spot sizes (mmxmm)	Dual 810b: 13.5x15 Quad 810b:14.5x25.5	10x10 18x10	The spot size of the proposed device is different from the spot sizes of the predicate device. The Leaseir Dual 810b and Quad 810b spots are larger than predicate device (This statement is taking in account that there are two available spot sizes for both subject and predicate device, the Leaseir Dual 810b 13,5x15 is larger than Elysion 10x10, as well as Quad 810b 14,5x25,5 is larger than Elysion 18x10). Fluence is lowered with increasing spot size to heat dermal targets effectively and to avoid side effects in the epidermis and

Parameters for Substantial Equivalence	Subject Device Leaseir MHR Xcell	Predicate Device Elysion-Pro	Remarks
510(k) Number	**N/A**	**K193367**	
			the upper dermis. The spot size and fluence have been adjusted accordingly. Hence, the safety and effectiveness of the device would not get affected. Also, the non-clinical tests conducted for the device, renders the device to be safe and effective.
Fluence	Dual 810b: 60J/cm^2 Quad 810b: 48J/cm^2	70J/cm^2	Fluence is a key factor in laser therapy. The fluency of the proposed device is slightly different from the fluency of the Elysion-pro. However, the maximum fluence limited by the software remains exactly same. The spot sizes and fluence are adjusted to heat dermal targets effectively. The non-clinical testing conducted for the device, demonstrates that the subject device is safe and effective for the proposed indications for use.
Maximum Fluence limited by the software (as per the treatment table)	40J/cm^2	40J/cm^2	SE
Frequency	Static: Up to 4 Hz Dynamic: 10 Hz	Static: Up to 3 Hz Dynamic:5-15 Hz	The frequency for the proposed device is slightly different from predicate device. However, the frequency range for the proposed device can be covered in the range of predicate device. Therefore, this difference will not affect substantial equivalence between proposed device and equivalent device. The justification in combination with the non-clinical testing demonstrates the safety and equivalence of the subject device
Pulse Duration	1-400ms	3 – 400ms	SE
Optical Peak Power (W)	4000 W	2000 W	Power and spot size are individual parameters that, when combined, provide power density. This combination defines how much energy and heat are delivered to the desired target. A general rule is that when the spot size is increased by half, the fluence should be decreased by half to create an effect at the same treatment depth because of the scattering of the incident beam. The laser diode power was calculated to achieve the same fluence when compared to the predicate device, maintaining the pulse durations

Parameters for Substantial Equivalence	Subject Device Leaseir MHR Xcell	Predicate Device Elysion-Pro	Remarks
510(k) Number	**N/A**	**K193367**	
Treatment mode	Static and Dynamic	Static and Dynamic	SE
Tissue cooling	Contact continuous, liquid cooled	Contact continuous, thermo-electrical	The difference between the subject device and the predicate is the method to cool down the tip. The predicate uses a TEC (Thermo Electric Cooling) that consists of a semiconductor device that maintains temperature difference between two parallel planes when an electrical current is applied. In the case of the Leaseir MHR Xcell, a tank of coolant is refrigerated by a phase-change cooler. This results in amount of coolant at a temperature between -6 and -2 Celsius degrees available to cool down different parts of the system when necessary. The coolant is pumped to the laser head and applied part tip by pipes through the umbilical cord. Cooling is an important part of the process, particularly for patient comfort and customer satisfaction. The slight difference between the cooling temperature of subject device and predicate device does not affect the safety and effectiveness of the device
Cooling Temperature	-4ºC to +4ºC	5ºC	
User Interface	LCD touchscreen	LCD touchscreen	SE
Pulsing Control	Finger switch	Finger switch	SE
Removable Applicators	Set of 2 removable applicators, Dual 810b and Quad 810b	Set of 3 removable applicators	The subject and predicate devices differ in the number of applicators provided. The different applicators are intended to give the user the chance to change the laser aperture spot in order to fit the areas of the body to be treated. Both devices provide spot sizes that are suitable for all the body areas to be treated and are capable to maintain the necessary energy density on the spot, hence this difference does not raise any difference in safety and effectiveness of the device.
Configuration	Main unit and hand pieces	Main unit, handpiece, and foot control (optional)	SE

Parameters for Substantial Equivalence	**Subject Device**	**Predicate Device**	**Remarks**
	Leaseir MHR Xcell	**Elysion-Pro**	
510(k) Number	**N/A**	**K193367**	
Power Supply	Single phase	Single-phase	The predicate device covers a wider power supply range (100-240V 50/60Hz) that covers all the different ac mains configurations. The Leaseir MHR Xcell is intended to work in specific supply ranges, providing two different device models, the 110b and the 220b. The US market will be covered by the 110b model, with a power supply range of 100-130V 50/60 Hz that works on the US voltages (120V +/-6%). This model is the subject of the present submissions. The 220b will not be marketed on the US, hence is not considered in this submission.
	100-130V	100-240V	
	50/60 Hz	50/60 Hz	
Dimension (HxWxD)	1100x450x570mm	650x500x450mm	The dimension and weight for the proposed device is different from predicate device. However, the dimension and weight are physical specifications, and this difference does not raise any issues in safety and effectiveness of the subject device.
Weight	48Kg	38Kg	

Indication for use statements of both the proposed and the predicate device are compared in the following table,

Table 3 Comparison of Intended Use

Parameter	**Subject Device**	**Predicate Device**	**Remarks**
	Leaseir MHR Xcell	**Elysion-Pro**	
Indications for use	Indications for use for Leaseir MHR Xcell diode laser hair removal system with 810nm applicator includes: • Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. • Treatment of Pseudofolliculitis barbae (PFB) • Use on all skin types (Fitzpatrick I-VI)	Indications for use for ELYSION diode laser hair removal system with 755nm and 810nm applicators include: Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. Treatment of Pseudofolliculitis barbae (PFB) Use on all skin types (Fitzpatrick I-VI).	Similar. Since Leaseir MHR Xcell used two applicators with 810nm wavelength. Also Leaseir MHR Xcell has two modes (Static and Dynamic) which is equivalent to Predicate device Elysion-Pro.

7. Harmonized Standards Complied

Table 4 Standards Complied by Subject and Predicate Device

S. No.	Standard	Subject Device	Predicate Device
	Electrical Safety/Radiation Safety		
1	IEC 60601-1	Pass	Pass
2	IEC 60601-1-2	Pass	Pass
3	IEC 60601-2-22	Pass	Pass
4	IEC 60825-1	Pass	Pass
	Software in a Medical Device		
5	IEC 62304	Pass	Pass
	Risk Analysis		
6	ISO 14971	Pass	Pass
	Biocompatibility		
7	ISO 10993-1	Pass	Pass

8. Comparison Summary

8.1 Intended Use

The intended use of the subject and predicate device is the same.

8.2 Similar characteristics

From the above comparative tables, the proposed medical device has the same intended use of hair removal and treatment of pseudo folliculitis barbae on all skin types (Fitzpatrick I-VI), as the predicate device and has similar technological characteristics.

Mechanism of action of all the devices (predicate and the new device) is photothermolysis, i.e., destruction of a follicle due to an increase of the temperature induced by a high-powered beam of light which is selectively absorbed by the melanin.

The subject and predicate device have the same configuration of Main Unit, Handpiece, LCD User Interface, Pulsing Control, and the laser energy is delivered through the applicator by means of a Finger Switch. Principle of operation of all the devices is using same energy source laser diode and the material of the laser diode is AlGaAs, which is same for the subject device and the predicate device. The laser contacting part of the applicator/handpiece is Sapphire for all the devices and the material of the sapphire is Al_2O_3 which is same for the subject and predicate device. The treatments modes (Static and Dynamic modes) between the subject and predicate device are found to be the same. Leaseir MHR Xcell has the pulse duration equivalent to the predicate device.

8.3 Differences

As explained in the Substantial Equivalence Table the differences do not substantially alter the intended use as both are non-invasive aesthetic laser for use in surgical applications in the medical specialties.

9. Non-Clinical Testing

Testing conducted to evaluate the functional performance and safety of the Leaseir MHR Xcell equipment. The test results demonstrated that the proposed device complies with the following standards:

1. ANSI AAMI ES60601-1:2005/(R)2012 with amendments Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
2. IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
3. IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes.
4. IEC 60601-2-22 Edition 3.1 2012-10 Medical electrical equipment - Part 2-22: Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
5. IEC 60825-1 Edition 2.0 2007-03 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007).
6. ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices.
7. IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices.
8. ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

10. Substantial Equivalence Conclusion

Based on the above technological specification comparison and justifications of the differences provided, the subject device is determined to be substantially equivalent to the predicate device.