May 4, 2026

Leaseir Technologies, Slu
℅ Sergio Santiago
CTO & Official Correspondent, Leaseir
Paladin Medical, Inc.
415 Valley View Trl.
Houlton, Wisconsin 54082

Re: K253251
Trade/Device Name: Leaseir MHR Xcell (console) (MHR-100b); Handpiece: Dual (810-b and Blend-b); Handpiece: Quad (810-b and Blend-b)
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: September 26, 2025
Received: September 29, 2025

Dear Sergio Santiago:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.05.04 15:36:36 -04'00'

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253251

Please provide the device trade name(s).

Leaseir MHR Xcell (console) (MHR-100b);
Handpiece: Dual (810-b and Blend-b);
Handpiece: Quad (810-b and Blend-b)

Please provide your Indications for Use below.

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

Hair Removal with Statis 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)

Treatment of benign vascular lesions

Treatment of benign pigmented lesions

Indications for use for the Leaseir MHR Xcell diode laser system with 810-1060nm 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-rowing 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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253251

510(k) Summary

Prepared on: 2026-04-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Leaseir Technologies, SLU
Applicant Address	Jimena de la Vega 140 1G CP Gijon Asu 33203 Spain
Applicant Contact Telephone	+34625391501
Applicant Contact	Sergio Camacho Santiago
Applicant Contact Email	scamacho@leaseir.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Leaseir MHR Xcell (console) (MHR-100b); Handpiece: Dual (810-b and Blend-b); Handpiece: Quad (810-b and Blend-b)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K214049	Leaseir MHR Xcell	GEX
K241656	Eneka Selectif	GEX
K112031	Alma Lasers Modified Diode Laser Module with SHR Treatment Mode	GEX

Device Description Summary

21 CFR 807.92(a)(4)

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 controlling emission of laser radiation to the target tissue.

The principle of operation consists of the photons traveling 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, delivers a continuous pulse pattern while the button is pressed. As previously, 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). This Special 510(k) for the Leaseir MHR Xcell adds two additional applicators. The primary predicate for this Special 510(k) is the Leaseir MHR Xcell. The subject of this submission therefore concerns certain software updates to the same main console which allow the four interchangeable applicators (two new.) Software updates are intended to allow the software to recognize the new handpiece models that deliver a

different wavelength, in order to be able to provide the proper information on the available laser parameters to the user through the screen. Also, this is an opportunity to deploy minor upgrades to software that were previously identified. Risk management documentation provided in the submission demonstrates the validation of these changes.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Indications for use for the Leaseir MHR Xcell diode laser 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)

Treatthent of benign vascular lesions

Treatment of benign pigmented lesions

Indications for use for the Leaseir MHR Xcell diode laser system with 810-1060nm 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-rowing 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 Comparison

21 CFR 807.92(a)(5)

The subject device and its predicates have the same intended use and the same indication for use.

Technological Comparison

21 CFR 807.92(a)(6)

There are no differences to the design, material, chemical composition, principle of operation or energy source compared to the predicate. The applicant of this Special 510(k) is the owner of the predicate device. The differences presented here are in order to offer two additional applicators. This submission provides full details as to how the changes, including those to software, do not introduce new risks.

The Leaseir MHR XCell diode laser system that is the subject of this 510k premarket notification is the same or similar in design, intended use, principles of operation, and technological characteristics, compared to the predicate devices. The minor differences in the subject device to the predicate does not raise new types of questions with regards to safety and effectiveness. The performance testing provided in this 510k support that the device can be used safely and effectively for the proposed indications for use.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

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:

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.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Function". Basic Documentation Level documentation was provided.

The Leaseir MHR XCell diode laser system that is the subject of this 510K is considered to be substantially equivalent to the predicate devices.