October 16, 2025

MateLaser, Inc.
Ruth Garcia
Quality Manager
3257 NW 7th Ave Cir
Miami, Florida 33127

Re: K250731
Trade/Device Name: MateLaser Medical Diode Laser Systems (ML-DLS-30)
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: NVK, ILY, EEG
Dated: September 19, 2025
Received: September 19, 2025

Dear Ruth Garcia:

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.

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)*

K250731

Device Name

MateLaser Medical Diode Laser Systems (ML-DLS-30)

Indications for Use *(Describe)*

(970nm and 445nm):Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement(removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.
Whitening(970nm and 445nm): For light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.
Low Level Laser Therapy(660nm and 970nm): To emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K250731

510(k) Summary

Prepared on: 2025-10-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MateLaser, Inc.
Applicant Address	3257 NW 7TH AVE CIR, Miami FL 33127
Applicant Contact Telephone	1-305-770-6036
Applicant Contact	Ruth Garcia
Applicant Contact Email	ruth.garcia@matelasers.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	MateLaser Medical Diode Laser Systems (ML-DLS-30)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Laser, Dental, Soft Tissue
Regulation Number	878.4810
Product Code(s)	NVK, ILY, EEG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180044	SIROLaser Blue	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The 445nm, 970nm and 660nm laser radiation of the MateLaser is generated via different laser diodes inside the control unit and guided to the treatment region via quartz fibers. The laser radiation is absorbed by the tissue and converted to heat used for cutting, coagulation, germ reduction and desensitization, muscle relief. The device primarily consists of the main unit, a fiber optic handlepiece, a Type-C cable, and a power adapter.

The device operates in two distinct emission modes: CW (Continuous Wave) mode, which provides a continuous, uninterrupted laser beam and ISP (pulse) mode, which interrupts the laser beam at regular intervals with adjustable duty cycles. The MateLaser Medical Diode Laser Systems (Model ML-DLS-30) features a home screen interface that allows operators to configure treatment parameters including wavelength selection (445nm, 660nm, or 970nm), power settings, duty cycle, frequency, and treatment time. During operation, users navigate through the home screen to set parameters, switch from standby to ready mode, and initiate laser emission while monitoring battery status, total energy output, and treatment countdown. The device specifications include optical power ranges of 0.2-3W for 445nm and 970nm wavelengths and 25-100mW for 660nm.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

(970nm and 445nm):Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed

soft tissue within the periodontal pocket; sulcular debridement(removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.
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Low Level Laser Therapy(660nm and 970nm): To emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same between proposed device and predicate device .

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device MateLaser Medical Diode Laser Systems products has the same purpose as the predicate device: product code, Regulation No., Class , Laser Classification, Laser Type, Laser Wavelength , Peak Power , Repetition Rate , Pulse duration , Optical Fiber Surgical Tips , Laser Handpiece , Laser Therapy Light Guides , Aiming Beam, Laser Control Unit User Interface, Type of Use and Electromagnetic compatibility and electrical safety compliance.
The difference only exists in such contents:
Activation Method and Laser Control Unit Dimensions. These items can be controlled within the scope of application. These small differences between the proposed devices and predicate devices do not cause new safety and effectiveness problems. According to the non clinical test results, 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

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The bench tests include:
Performance Test (Appearance module; Package Module; Functional Module; Electrical Safety Test; Reliability Module；Verification Report for the Compatibility and Matching Performance of Purchased Optical Fiber Tip&Light Guide with the product).
The device passed all the tests mentioned above. Based on these tests results, manufacturer believes that MateLaser Medical Diode Laser Systems ML-DLS-30 is substantially equivalent to the predicate device without raising new safety and effectiveness issues. Performance test reports are attached.

The Testing to verify the performance requirements of the MateLaser Medical Diode Laser Systems was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.
Tests included in this premarket notification:
Testing to verify the conformity of the proposed MateLaser Medical Diode Laser Systems with the requirements of IEC 60601-1: (Medical electrical equipment Part 1: General requirements for basic safety and essential performance).
Testing to verify the conformity of the proposed MateLaser Medical Diode Laser Systems with the requirements of IEC 60601-1-2: (Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic compatibility).
Testing to verify the conformity of the proposed MateLaser Medical Diode Laser Systems to IEC 60825-1 (Safety of laser products – Part 1: Equipment classification and requirements).
Testing to verify the performance of the proposed MateLaser Medical Diode Laser Systems according to IEC 60601-2-22: (Medical electrical equipment Part 2: Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment).
Validation of the device's software in conformity with IEC 62304 (Medical device software – Software lifecycle processes).
Biocompatibility testing was conducted on a handlepiece accessory that contacts the patient's oral cavity. In accordance with FDA biocompatibility guidance based on ISO 10993-1, five tests were performed (cytotoxicity, skin sensitization, irritation, pyrogenicity, and acute systemic toxicity) and all demonstrated that the device meets safety requirements for its intended use.
The MateLaser Medical Diode Laser Systems theme equipment comes into contact with patients with accessories (fiber tips and Physiotherapy Treatment head) that are not included in the shipment. The user manual provides specifications for compatible accessories (fiber tips and Physiotherapy Treatment head) for users to refer to when purchasing compatible accessories.

The reprocessing validation studies for both the MateLaser Medical Diode Laser Systems and handlepiece accessory were conducted, evaluating comprehensive cleaning, disinfection, and sterilization of the subject device. Both devices successfully manual cleaning validation using dental test soil, achieved required log reductions against bacterial challenge organisms through disinfection validation and for the handlepiece additionally validated for steam sterilization demonstrating a SAL of 10^-6. Reprocessing validation was conducted per the FDA Reprocessing guidance.

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.