May 29, 2026

Eufoton S.R.L.
Andrea Buoso
Quality manager
Via Flavia 23/1
Trieste, IT 34148
Italy

Re: K260489
Trade/Device Name: LASEmaR 1500 (LASEmaR 1500)
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 30, 2026
Received: April 30, 2026

Dear Andrea Buoso:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.05.29 12:55:23 -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

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.

510(k) Number *(if known)*
K260489

Device Name
LASEmaR 1500

Indications for Use *(Describe)*
The LASEmaR 1500 laser system (and the fiber delivery systems and accessories) is indicated for surgical applications requiring vaporization, incision, excision, ablation, cutting, and hemostasis or coagulation (in combination with endoscopy equipment) for medical specialties including: Plastic/Aesthetic Medicine, ENT, Gynecology and Neurosurgery and Laser assisted Lypolysis.

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) Summary

Trade/Device Name: LASEmaR 1500 | 510(k) Number: K260489

I. Submitter

Submitter	Eufoton S.r.l.
Address	Via Flavia 23/1, 34148 Trieste (TS), Italy
Telephone	+39 040 9899082
Contact Person	Andrea Buoso
Date Prepared	April 20, 2026

II. Device Identification

Trade/Proprietary Name	LASEmaR 1500
Common or Usual Name	Powered Laser Surgical Instrument
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number	21 CFR 878.4810
Product Code	GEX
Regulatory Class	Class II

III. Predicate Device

Predicate Device	Lasemar 1500
Manufacturer	Eufoton S.r.l.
510(k) Number	K092860

IV. Device Description

The LASEmaR 1500 is a diode laser surgical system intended for soft tissue applications. The device includes an electronic console that manages a gallium arsenide (GaAs) diode laser emitting at 1470 nm with a maximum output power of 15 W. The system also incorporates a red visible aiming beam at 650 nm with a maximum output of 5 mW to identify the treatment site. Laser energy is delivered through compatible optical fibers and accessories, including handpieces. The device can be operated in continuous wave (CW) and pulsed modes, with user-selectable parameters including power, pulse duration, pulse repetition frequency, and number of pulses, and activation controlled by a footswitch. The system includes software-assisted menus, a 7-inch touchscreen display, an AC/DC power supply, and an active cooling system. The LASEmaR 1500 is intended for use only with compatible Eufoton fibers equipped with RFID technology to identify accessory information and use parameters.

V. Intended Use / Indications for Use

The LASEmaR 1500 laser system (and the fiber delivery systems and accessories) is indicated for surgical applications requiring vaporization, incision, excision, ablation, cutting, and hemostasis or coagulation (in combination with endoscopy equipment) for medical specialties including: Plastic/Aesthetic Medicine, ENT, Gynecology and Neurosurgery and Laser assisted Lypolysis.

VI. Technological Characteristics

The subject device and the predicate device share the same fundamental intended use, regulatory classification, and principle of operation as powered laser surgical instruments for soft tissue applications. Both devices deliver laser energy through compatible fiber delivery systems and accessories for cutting, ablation, vaporization, and coagulation/hemostasis of soft tissue in surgical settings. The subject device uses the same fundamental diode laser technology, including 1470 nm laser emission delivered through fiber optics, and includes a visible aiming beam. Any differences between the subject and predicate devices do not alter the fundamental scientific technology and do not raise new questions of safety and effectiveness.

VII. Nonclinical Performance Data

Nonclinical performance evaluation included bench testing demonstrating that the subject device performs according to predetermined specifications for laser output and functional operation. The nonclinical package also included biological safety assessment of applicable patient-contacting components and accessories, including biocompatibility endpoints, as applicable to the submitted configuration.

VIII. Clinical Performance Data

Clinical performance data were not required to support substantial equivalence for this submission.

IX. Conclusion

Based on the intended use, technological characteristics, and nonclinical performance information provided, the LASEmaR 1500 is substantially equivalent to the predicate device identified above. The subject device has the same intended use and the same fundamental scientific technology as the predicate device and does not raise new questions of safety and effectiveness. Therefore, the LASEmaR 1500 is as safe and effective as the predicate device for the stated intended use.