March 17, 2026

Elesta S.P.A
% Jenifer Ulrikson
Associate Attorney
DuVal & Associates
825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: K260632
Trade/Device Name: Laser Thermal Therapy Kit
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: February 26, 2026
Received: February 26, 2026

Dear Jenifer Ulrikson:

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), 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 Medical Device File (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: 2026.03.17 17:03:05 -04'00'

Tanisha L. 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.

510(k) Number *(if known)*
K260632

Device Name
LASER THERMAL THERAPY KIT

Indications for Use *(Describe)*
The LASER THERMAL THERAPY KIT is used to direct laser energy to soft tissue, to vaporize, ablate, necrotize or coagulate soft tissue through interstitial irradiation in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, at a wavelength of 1064nm.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

LASER THERMAL THERAPY KIT Special 510(k)
Prepared on 3/16/2026

This 510(k) summary is being submitted as required by 21 CFR 807.92.

1. General Information

Applicant: ELESTA SPA
+39 055 776 0190
Legal Office: Via Baldanzese 17, Calenzano (FI) 50041, Italy
Operative Site: Via Arsiero Salvanti 41/43, Calenzano (FI) 50041, Italy

Establishment registration number: 3015077548

Contact for this application:
Jenifer Ulrikson, J.D., RN
Associate Attorney, DuVal & Associates
825 Nicollet Mall, Suite 1820
Minneapolis, MN 55402
Office: 612.338.7170
Cell: 763-691-3904
email: ulrikson@duvalfdalaw.com

2. Device

Trade name: LASER THERMAL THERAPY KIT

Classification name: Powered Laser Surgical Instrument (GEX)

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)

Product Code: GEX

Class: II

3. Predicate Devices

LASER THERMAL THERAPY KIT is substantially equivalent to the following device (Predicate device 1):

Applicant	Device name	510(k) Number
ELESTA SPA	LASER THERMAL THERAPY KIT	K230460

And to the accessories cleared inside (Predicate device 2):

Applicant	Device name	510(k) Number
El.En Electronic Engineering	ECHOLASER X4	K181510

The subject device has same technological characteristics, materials, chemical composition, principle of operation, energy source, and biocompatibility as the predicate LASER THERMAL THERAPY KIT (K230460) and the fiber optic and introducer needle accessories of predicate ECHOLASER X4 (K181510).

4. Comparison of Technological Characteristics

	Subject Device	Primary Predicate Device K230460	Secondary Predicate Device K181510	Comparison
Product Name	LASER THERMAL THERAPY KIT	LASER THERMAL THERAPY KIT	ECHOLASER X4	N/A
Manufacturer	Elesta SpA, Italy	Elesta SpA, Italy	El.En Electronic Engineering SpA, Italy	N/A
Indication for Use	The LASER THERMAL THERAPY KIT is used to direct laser energy to soft tissue, to **vaporize, ablate**, necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery, in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, plastic surgery, orthopedics, pulmonology, radiology, and urology at a wavelength of 1064nm.	The LASER THERMAL THERAPY KIT is used to direct laser energy to soft tissue, to necrotize and coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery, in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, plastic surgery, orthopedics, pulmonology, radiology, and urology at a Wavelength of 1064nm.	The E C H O L A S E R X4 laser system is intended for use in cutting, vaporization, ablation and Coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes cystoscopes and colonoscopies), in incision/excision, **vaporization, ablation and coagulation of soft tissue** in contact and non-contact open surgery (with or without a handpiece), and in the treatment and/or removal of vascular lesions (tumors).	Primary and Secondary Predicate: E q u i v a l e n t . Subject device's indications for use incorporate laser modalities from each predicate for use at 1064 nm.

	Subject Device	Primary Predicate Device K230460	Secondary Predicate Device K181510	Comparison
Device Regulatory Classification	Accessory to Powered surgical laser instrument FDA 878.4810	Accessory to powered surgical laser instrument FDA 878.4810	Powered surgical laser instrument FDA 878.4810	Primary Predicate: Same classification, accessory to surgical laser instrument used as comparator Secondary Predicate: Same
Product Code	GEX	GEX	GEX	Primary and Secondary Predicate: Same
Device Class	Class 2	Class 2	Class 2	Primary and Secondary Predicate: Same
Fiber Core Diameter	272 µm	272 µm	272 µm	Primary and Secondary Predicate: Same
Fiber Length	2mt	2mt	2mt	Primary and Secondary Predicate: Same
Proximal Connector	SMA 905	SMA 905	SMA 905	Primary and Secondary Predicate: Same
Wavelength	1064 nm	1064 nm	1064 nm	Primary and Secondary Predicate: Same
Laser Operation mode	Continuous Wave	Continuous Wave	Continuous Wave	Primary and Secondary Predicate: Same
Lesion Shape	Elliptical shape	Elliptical shape	Elliptical shape	Primary and Secondary Predicate: Same
Max Power	7W	7W	7W	Primary and Secondary Predicate: Same
Introducer Needle	Stainless steel	Stainless steel	Stainless steel (accessory)	Primary Predicate: Same Secondary Predicate: Same (accessory used as comparator)
Sterile Packaging Dimensions	Fiber Optic for PLA: 250x380 mm Introducer Needle: 75x400 mm	Fiber Optic for PLA: 300x570 mm Introducer Needle: 75x400 mm	Fiber Optic for PLA: 250x380 mm Introducer Needle: 75x400 mm	Primary Predicate: Introducer needle is same, Fiber Optic is equivalent to improve handling with the same

	Subject Device	Primary Predicate Device K230460	Secondary Predicate Device K181510	Comparison
				testing still applicable. Secondary Predicate: Same
External Stopper Diameter of Introducer	7.2 mm	9.9 mm	9.9 mm	Primary and Secondary predicate: Equivalent; no impact on the use of the device or technical performance.
Needle Protection Tube Length of Introducer	222 mm	222 mm or 132 mm	222 mm or 132 mm	Equivalent to long dimension of primary and secondary device.
Sterility	ETO	ETO	ETO	Primary and Secondary Predicate: Same
Fiber tip	Bare tip	Bare tip	Bare tip	Primary and Secondary Predicate: Same
Use	Single use	Single use	Single use of accessories (Fiber Optic and Needle)	Primary Predicate: Same Secondary Predicate: Same (accessory used as comparator)
Components	Fiber Optic Introducer Needle	Fiber Optic Introducer Needle	Laser and Fiber Optic Introducer Needle	Primary Predicate: Same Secondary Predicate: Equivalent; ECHOLASER X4 contains fiber optic and needle introducer

5. Device description

The LASER THERMAL THERAPY KIT is used to transfer laser energy from the laser unit to the tissue site for the treatment.

The energy is transmitted via the fiber optic, which is introduced into the skin and tissue site percutaneously using the introducer needle.
The LASER THERMAL THERAPY KIT is composed of a Fiber Optic for PLA (272 m core quartz-quartz fiber with distal end outer diameter 420 m and NA 0.2, and 2 m length) and an introducer needle (21G).
The device is sterile and single use.
Fiber optic and Introducer are packed individually.

6. Indications for Use

Indication for Use: The LASER THERMAL THERAPY KIT is used to direct laser energy to soft tissue, to vaporize, ablate, necrotize or coagulate soft tissue through interstitial irradiation in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, at a wavelength of 1064nm.

7. Performance data (non-clinical)

No additional performance testing was needed since the subject and predicate devices are identical in technological characteristics.

8. Conclusion

The technological characteristics and performance data including biocompatibility, sterility and shelf-life testing are exactly the same as cleared under K230460.

Thus, the LASER THERMAL THERAPY KIT is substantially equivalent to the cleared predicate devices and it does not pose any new risks or alter the safety profile of the subject device.