May 3, 2022

Elesta Spa
℅ Maurizio Pantaleoni
RA/QA Consultant
Maurizio Pantaleoni
Via Borgo Santa Cristina 12
Imola, Bologna 40026
Italy

Re: K213594
Trade/Device Name: Echolaser X4
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 4, 2022
Received: April 6, 2022

Dear Maurizio Pantaleoni:

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)*
K213594

Device Name
ECHOLASER X4

Indications for Use *(Describe)*
The ECHOLASER X4 laser system is indicated for use to 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 1064 nm.

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.

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510(k) Summary

1. General Information

Applicant: ELESTA SpA
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Tel. +39 055 8826807
Fax +39 055 7766698

Establishment Registration Number: 3015077548

Contact for the application: Maurizio Pantaleoni
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Imola (BO) 40026 , Italy
Tel. +39 3484435155
Email: maurizio.pantaleoni@gmail.com

Summary Preparation Date: October 22, 2021

2. Name & Classification

Common Name/Trade Name/Device Name: **ECHOLASER X4**

Classification names **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

Predicate	Applicant	Device name	510(k) Number
Primary	EL.EN. ELECTRONIC ENGINEERING SPA	ECHOLASER X4	K181510
Reference	Medtronic Navigation Inc.	Visualase Thermal Therapy System	K181859

The device modification is related to the ECHOLASER X4, already cleared by the Agency with K181510.

Requested change is related to a language revision of the Intended use of ECHOLASER X4, in order to reflect the description of applications of a predicate device which was unavailable at the time of the previous submission K181510. A reference predicate (K181859) is provided in support of the change in the intended use language.

No other changes have been made to the existing ECHOLASER X4 cleared by the Agency under K181510.

The technical features, the design, the performance and safety of the ECHOLASER X4 device are not affected by this device modification since they are precisely the same .

4. Device description

The ECHOLASER X4 is a medical device equipped with a diode laser source emitting at 1064nm wavelength in CW mode. The laser beam is transmitted via optical fibers . The operator can use 1 to 4 (or 1 to 2 in case of two channels model) fibers simultaneously, one independent from the other in both activation and power adjustment. Laser activation is controlled by footswitch.

5. Indications for Use

The ECHOLASER X4 laser system is indicated for use to 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.

Explanation of Differences: The above indications for use language is different than the indications for use language present in the primary predicate K181510. However, the intended use of the subject and predicate devices is identical (i.e., thermal destruction of the soft tissue of interest). Moreover, the modified language is comparable to the language present in the indications for use of the reference predicate and does not raise different questions of safety and effectiveness.

6. Summary of Technological Similarities/Differences

The device modification is related to the language revision of the Intended use of ECHOLASER X4. No other relevant changes have been made to the existing ECHOLASER X4 cleared by the Agency under K181510.

	Subject Device	**Primary Predicate Device**	**Comments**
Product Name	**ECHOLASER X4**	**ECHOLASER X4**	NA
510(K) No.	K213594	K181510	NA
Applicant	Elesta SpA	El.En. SpA	NA
Classification	21 CFR§878.4810, Laser Surgical Instrument for	21 CFR§878.4810, Laser Surgical Instrument for Use in	Identical

	Subject Device	Primary Predicate Device	Comments
	Use in General and Plastic Surgery and in Dermatology	General and Plastic Surgery and in Dermatology	
Product Code	GEX	GEX	Identical
Indications for Use	The ECHOLASER X4 laser system is indicated for use to 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.	The ECHOLASER 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).	Comparable, do not raise different questions of safety and effectiveness since the intended use are the same.
Laser Type	DIODE	DIODE	Identical
Wavelength (µm)	1064 nm ± 10%	1064 nm ± 10%	Identical
Output mode	Multimode	Multimode	Identical
Maximum delivered Power	28W (up to 7 W for each laser fiber)	28W (up to 7 W for each laser fiber)	Identical
Stability of the output power level	±20%	±20%	Identical
Mode of operation	Continuous wave	Continuous wave	Identical
Output power increments	0.5W	0.5W	Identical
Cooling	TEC	TEC	Identical
Emission	Controlled by footswitch	Controlled by footswitch	Identical
Aiming Beam • Laser Type • Wavelength • Maximum Delivered Output Power	Diode 630-670 nm < 3 mW	Diode 630-670 nm < 3 mW	Identical
Output port	SMA 905	SMA 905	Identical
Introducers	Elesta – El AG2 020 620 Elesta – El AG2 0020 640	Biopsybell TR2111.9EC Biopsybell TR2120.8EC	Comparable in material, construction, and processing and thus do not raise different questions of safety and effectiveness.
Laser Type (per IEC 60825-1)	Class 4	Class 4	Identical

	Subject Device	Primary Predicate Device	Comments
Laser Safety Classification FDA	Class 2	Class 2	Identical
Power source (General)	110-120V AC / 50-60Hz	110-120V AC / 50-60Hz	Identical
Operating temperature range	10ºC – 35ºC	10ºC – 35ºC	Identical
Emergency switch	Yes	Yes	Identical
Key activation of laser output	Yes	Yes	Identical
Remote Interlock	Yes	Yes	Identical
Power ON/OFF visual indicator	Yes	Yes	Identical
Laser emission Indicator	Yes	Yes	Identical
Internal laser power monitor	Yes	Yes	Identical
Fiber insertion interlock	Yes	Yes	Identical
Audio warning signal level	Fixed at HIGH	Fixed at HIGH	Identical

7. Non-Clinical Testing

The following non-clinical tests were performed:

i) Biocompatibility assessment per ISO 10993.

No additional non-clinical testing is needed since the subject device is identical to the primary predicate.

8. Clinical Testing

No additional clinical testing is needed since the subject device is identical to the primary predicate.

9. Conclusions

In light of evidence summarized above and based on classification, intended use, technological characteristics and performance data, the subject device is substantially equivalent to the primary predicate device.