August 19, 2026

Elesta S.P.A
% Jessica Czamanski
Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
825 Nicollet Mall
Suite 1820
Minneapolis, Minnesota 55402

Re: K261964
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: June 11, 2026
Received: June 11, 2026

Dear Jessica Czamanski:

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: 2026.08.19 16:46:45 -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)*
K261964

Device Name
ECHOLASER X4

Indications for Use *(Describe)*
The ECHOLASER X4 laser system is indicated for use to cut, 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 1064 nm.
Echolaser X4 laser system includes the following specific indications:
Discectomy:
- Percutaneous Lumbar Discectomy

Gastrointestinal:
- Tissue Ablation: Benign and malignant Neoplasm

Prostatectomy:
- Soft Tissue Coagulation: Benign Prostatic Hyperplasia (BPH prostatectomy)

Pulmonary Surgery:
- Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system.
  Examples include: Benign and malignant pulmonary obstruction

GENERAL SURGERY
- Soft Tissue:
  Tumors and Lesions
  Tissue Ablation

GENITOURINARY SURGERY Ablation and Hemostasis:
- Superficial Urinary Bladder Tumors
- Invasive Bladder Carcinoma

GYNECOLOGICAL TISSUE ABLATION
- Endometrial Ablation (menorrhagia)
- Submucous Fibroids

OTORHINOLARYNGOLOGY SURGERY
- Soft Tissue:
  Tumors and Lesions
  Tissue Ablation

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 K261964

ECHOLASER X4 Traditional 510(k)
Prepared on 08/06/2026

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:
Jessica Czamanski, RAC
Regulatory, Quality, and Compliance Consultant, DuVal & Associates
825 Nicollet Mall, Suite 1820
Minneapolis, MN 55402
Office: 612.338.7170
Cell: 754.422.9101
email: jczamanski@duvalfdalaw.com

2. Device

Trade name: ECHOLASER X4

Classification name: Powered Laser Surgical Instrument

Regulation Name & Number: 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

ECHOLASER X4 is substantially equivalent to the following devices:

Applicant	Device name	510(k) Number	Use
ELESTA SPA	ECHOLASER X4	K213594	PRIMARY PREDICATE
QUANTA SYSTEM SPA	QUANTA1064 Quanta Diode Laser Family	K100558	SECONDARY PREDICATE
LAMBDA SPA	DOCTOR DIODE Laser Family	K102036	REFERENCE

The Subject Device has same technological characteristics, materials, chemical composition, principle of operation, energy source, and biocompatibility as the Predicate ECHOLASER X4 (K213594) and equivalent

technological characteristics, principle of operation, energy source and mode of use of Predicate QUANTA 1064 (K100558).

4. Comparison of Technological Characteristics

	SUBJECT DEVICE (K261964)	PRIMARY PREDICATE DEVICE (K213594)	SECONDARY PREDICATE DEVICE (K100558)	REFERENCE DEVICE (K102036)	Comments
Product name	**ECHOLASER X4**	**ECHOLASER X4**	**Quanta1064 - Quanta Diode Laser Family**	**Doctor Diode Laser Family**	-
510(k)	*K261964*	*K213594*	*K213594*	*K102036*	-
Applicant	ELESTA S.p.A.	ELESTA S.p.A.	QUANTA SYSTEM S.p.A.	LAMBDA S.p.A.	-
Classification	21 CFR §878.4810	21 CFR §878.4810	21 CFR §878.4810	21 CFR §878.4810	SAME
Product Code	GEX	GEX	GEX	GEX	SAME
Indications for Use	The ECHOLASER X4 laser system is indicated for use to **cut, 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 1064 nm. **Echolaser X4 laser system includes the following specific indications:** **Discectomy** - **Percutaneous Lumbar Discectomy** **Gastrointestinal** - **Tissue Ablation: Benign and malignant Neoplasm** **Prostatectomy** - **Soft Tissue Coagulation: Benign Prostatic Hyperplasia (BPH prostatectomy)** **Pulmonary Surgery:** - **Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system.**	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 Quanta System QUANTA Diode Laser Family, including the QUANTA532, QUANTA808, QUANTA940, QUANTA980,QUANTA1064, QUANTA1320, QUANTA1470 and QUANTA1950 (and all their double wavelength combination and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the **vaporization,** incision, excision, **ablation, cutting** and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures. […] QUANTA1064 DERMATOLOGY/PLASTIC SURGERY Photocoagulation:	Doctor Diode Laser Family including Doctor Smile, Doctor Surgery and Helios are available at … 1064 wavelength with variable power of 500w, 2w, 2,5w , 5w, 7w, 8w, 10w and 15w (and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the **vaporization**, incision, excision, **ablation**, **cutting** and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gjnecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures [...] **Doctor Diode Laser Family at 1064mm wavelength:** DERMATOLOGY/PLASTIC SURGERY Photocoagulation: Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful) **Discectomy:** **Percutaneous Lumbar Discectomy** **Gastrointestinal:** **Tissue Ablation:**	The subject IFU is based on the IFUs of the predicate devices and is further supported by the reference device's IFU. This update adds specificity to the indication for the same general intended use.

	SUBJECT DEVICE (K261964)	PRIMARY PREDICATE DEVICE (K213594)	SECONDARY PREDICATE DEVICE (K100558)	REFERENCE DEVICE (K102036)	Comments
	Examples include: Benign and malignant pulmonary obstruction **GENERAL SURGERY** - **Soft Tissue: Tumors and Lesions Tissue Ablation** **GENITOURINARY SURGERY Ablation and Hemostasis:** - **Superficial Urinary Bladder Tumors** - **Invasive Bladder Carcinoma** **GYNECOLOGICAL TISSUE ABLATION** - **Endometrial Ablation (menorrhagia)** - **Submucous Fibroids** **OTORHINOLARYNGOLOGY SURGERY** - **Soft Tissue: Tumors and Lesions Tissue Ablation**		Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful) **Discectomy: Percutaneous Lumbar Discectomy** **Gastrointestinal: Tissue Ablation:** • **Benign and malignant Neoplasm** • Polyps • Colitis • Ulcers • Aniodysplasia • Hemorroids […] **GENERAL SURGERY Soft Tissue:** • Skin Incision • Tissue Dissection • Excision (external tumors and lesions) • Resection of Internal Organs (complete or partial) • **Tumors and Lesions** • **Tissue Ablation** Vessel Coagulation **GENITOURINARY SURGERY Ablation and Hemostasis:** • **Superficial Urinary Bladder Tumors** • **Invasive Bladder Carcinoma** • Urethral Strictures • Lesions of the External Genitalia **GYNECOLOGICAL TISSUE ABLATION** • **Endometrial Ablation (menorrhagia)** • Soft Tissue Excisional Conization • **Submucous Fibroids** • Polyps • Septa NEUROSURGERY […] **OTORHINOLARYNGOLOGY SURGERY Soft Tissue**: • Skin Incision • Tissue Dissection	• **Benign and malignant Neoplasm** • Polyps • Colitis • Ulcers • Aniodysplasia • Hemorroids **Prostatectomy: Soft Tissue Coagulation:** • **Benign Prostatic Hyperplasia (BPH Prostatectomy)** **Pulmonary Surgery: Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:** • **Tracheobronchial malignancy or stricture** • **Benign and malignant pulmonary obstruction** • **Endoscopic pulmonary applications** […] Endovenous Occlusion of the Greater Saphenous Vein in Patient with Superficial Vein Reflux […]	

	SUBJECT DEVICE (K261964)	PRIMARY PREDICATE DEVICE (K213594)	SECONDARY PREDICATE DEVICE (K100558)	REFERENCE DEVICE (K102036)	Comments
			• Excision (external tumors and lesions) • Resection of Internal Organs (complete or partial) • **Tumors and Lesions** • **Tissue Ablation** • Vessel Coagulation **Prostatectomy:** **Soft Tissue Coagulation*:*** • **Benign Prostatic Hyperplasia (BPH Prostatectomy)** POLMUNARY SURGERY Palliative Treatment: Benign and Malignant Pulmonary Airway Obstructions		
Laser Type	Diode	Diode	Diode	Diode	SAME
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm	SAME
Maximum delivered power	28W	28W	**30 W**	**15W**	SAME AS PRIMARY PREDICATE DEVICE and within the range of SECONDARY PREDICATE DEVICE and REFERENCE DEVICE
Stability of the output power	±20%	±20%	unknown	unknown	SAME AS PRIMARY PREDICATE DEVICE
Mode of operation	Continuous wave	Continuous wave	**Continuous wave,** PW	Continuous wave	SAME

5. 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 fibres. The operator can use up to 4 optical fibres simultaneously, one independent from the other in both activation and power adjustment. Laser activation is controlled by footswitch. The laser beam is transmitted via optical fibers, each identified by a colored connector containing an identification microchip; it is extremely easy to control from the touchscreen control panel which for each fiber displays a corresponding area in the same color. The optical fiber is guided to the target tissue with the aid of needle.

6. Indications for Use

The ECHOLASER X4 laser system is indicated for use to cut, 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 1064 nm.

Echolaser X4 laser system includes the following specific indications:
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  Examples include: Benign and malignant pulmonary obstruction

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GYNECOLOGICAL TISSUE ABLATION
- Endometrial Ablation (menorrhagia)
- Submucous Fibroids

OTORHINOLARYNGOLOGY SURGERY
- Soft Tissue:
  - Tumors and Lesions
  - Tissue Ablation

7. Performance data (non-clinical)

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

The Subject Device is compliant with the following Consensus Standards:

Recognition Number	Standard Number and Version	Standard Title	Compliance
19-49	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.	Declaration of Conformity
19-36	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]	Declaration of Conformity
12-356	IEC 60601-2-22 Edition 4.0 2019-11	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment	Declaration of Conformity
12-273	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)]	Declaration of Conformity
13-79	ANSI AAMI IEC 62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	Declaration of Conformity

8. Conclusion

The ECHOLASER X4 is substantially equivalent to the cleared Predicate Devices K213594 and K100558.