May 22, 2023

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

Re: K230460
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 17, 2023
Received: February 21, 2023

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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K230460

Device Name
LASER THERMAL THERAPY KIT

Indications for Use *(Describe)*
The LASER THERMAL THERAPY KIT used to direct laser energy to soft tissue, 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.

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.

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510(k) SUMMARY

K230460

The 510(k) Summary of the LASER THERMAL THERAPY KIT is provided on the next page. This 510(k) Summary is being submitted as required by 21 CFR 807.92.

1. General Information

Applicant: ELESTA SpA
Via Baldanzese, 17
Calenzano (FI)
Italy 50041, Italy
Tel. +39 055 8826807
Fax +39 055 7766698

Establishment Registration Number: 3015077548

Contact for the application: Maurizio Pantaleoni
Via Borgo Santa Cristina 12
Imola (BO) 40026, Italy
Tel. +39 3484435155
Email: maurizio.pantaleoni@gmail.com

Summary Preparation Date: February, 17 2023

2. Name & Classification

Device Name: LASER THERMAL THERAPY KIT

Classification names Accessory to powered surgical laser instrument (GEX)

Regulation Name Accessory to powered surgical laser instrument (21 CFR§878.4810).

Product Code GEX

CLASS: II

3. 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 LASER THERMAL THERAPY KIT consist of a Fiber Optic for PLA (272µm core quartz-quartz fiber with distal end outer diameter 420µm and NA 0.2) and an introducer needle (21G). The device is sterile and single use.

4. Indications for Use

The LASER THERMAL THERAPY KIT used to direct laser energy to soft tissue, 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 (e.g. Benign Prostatic Hyperplasia), at a wavelength of 1064nm.

5. Predicate devices

LASER THERMAL THERAPY KIT is substantially equivalent to the following device legally marketed in the U.S. market:

Applicant	Device name	510(k) Number
BioTex Inc., US	Visualase Laser fiber LDF	K053087

Complete substantial equivalence information is provided in the Section XII of this submission.

6. Reference Device

The LASER THERMAL THERAPY KIT consist of a Fiber Optic for PLA and an Introducer needle. For what concern the contact materials relevant for biocompatibility, the Fiber Optic for PLA is equivalent to the following device legally marketed in the U.S.

Furthermore the Echolaser X4 reference device was also cleared to be use used orthopaedics, as the subject device.

Applicant	Device name	510(k) Number
Oberon GmbH	Oberon Surgical Fibers	K140470
Elesta Spa	ECHOLASER X4	K213594

7. Comparison of technological characteristics with the predicate devices

	Subject Device	Primary predicate device
Product Name	LASER THERMAL THERAPY KIT	Visualase Laser fiber LDF
Manufacturer	Elesta SpA, Italy	BioTex Inc., US
Indication for Use	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, orthopaedics, pulmonology, radiology, and urology at a wavelength of 1064nm.	The LDF is indicated for use to 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, neurosurgery, plastic surgery, pulmonology, radiology, and urology, for wavelengths 800nm through 1064nm.
Device Regulatory Classification	Accessory to powered surgical laser instrument	Accessory to powered surgical laser instrument

	FDA 878.4810	FDA 878.4810
Product code	GEX	GEX
Device Class	Accessory to powered surgical laser instrument Class 2	Accessory to powered surgical laser instrument Class 2
510 (k) number	To be obtained	K053087
Fiber core diameter	272 μm	400 μm (200 – 1000)
Numerical Aperture	0.22	0.37
Proximal connector	SMA 905	SMA 905
Wavelength	1064 nm	532-1064nm
Laser Operation mode	Continuous Wave	Continuous Wave
Lesion shape	Elliptical shape	Ellipsoidal / Round
Max Power	7 W	8 W for 400μm

8. Non Clinical Performance test

Engineering studies has been executed on the device in order to assess and check the correct presence of the expected performances and its safety. These studies (eg effectiveness and efficiency of the laser light transmission of the fiber, including power loss, mechanical and optical functionalities test etc…) demonstrates that the device is effective in guiding and transmitting the laser light, emitted by the laser system, in order to efficiently emit it outside the fiber tip, in the target region of interest, without relevant power losses. Taking into account also the verified effectiveness of the fiber to be coupled to the 21G introducer needles showing a specific protrusion distance with a fixed tolerance, these fibers result able to accurately reach the target tissue thanks to the needle guidance and to allow a safe emission of the laser light without causing no indirect and undesired thermal damages to the patient.

Other tests has been furthermore performed, for the subject device, to validate ETHYLENE OXIDE sterilization in compliance with ISO 11135 requirements and shelf life, in compliance with the recognized standards ASTM F1980-16 and ASTM F1929-15. Finally data available allow also to confirm biocompatibility of the device in compliance with ISO10993-1 standard. Therefore, considering all the verifications performed, Elesta Laser Thermal Therapy Kit medical device, composed by Fiber Optic for PLA and Introducer Needle, shows and confirms all the expected performances required.

9. Conclusions

In light of evidences summarized above and based on classification, intended use and technological characteristics, the subject device is substantially equivalent to the identified predicate devices.