U.S. FOOD & DRUG ADMINISTRATION

September 4, 2018

El.En Electronic Engineering Spa
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, 50041 It

Re: K181510
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 5, 2018
Received: June 8, 2018

Dear Paolo Peruzzi:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181510

Device Name
ECHOLASER X4

Indications for Use *(Describe)*

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).

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

ECHOLASER X4

Submitter:

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Date Summary Prepared:

June 5, 2018

Device Trade Name:

ECHOLASER X4

Common Name:

Medical Laser system

Classification Name:

Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (GEX)

Classification Number:

21 CFR 878.4810

Equivalent Devices:

DORNIER MEDILAS D 1064 laser system (K080959).

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 1 to 4 optical fibres. The operator can use 1 to 4 fibres simultaneously, one independent from the other in both activation and power adjustment. Laser activation is controlled by footswitch.

Intended Use:

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).

Substantial equivalence discussion:

The ECHOLASER X4 is substantially equivalent to the DORNIER MEDILAS D 1064 laser system (K080959).

Device Trade Name	Proposed 510(k) Device **ECHOLASER**	Predicate Device K080959 **DORNIER MEDILAS D 1064**
Indications for Use	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).	The DORNIER MEDILAS D 1064 Laser Model 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).
Laser Type	DIODE	DIODE
Wavelength (µm)	1064 nm ± 10%	1064 nm ± 10%
Output mode	Multimode	Multimode
Maximum delivered Power	28W	30W
Stability of the output power level	±20%	±20%
Beam diameter	0.3 mm	0.3 mm
Mode of operation	Continuous wave	Continuous wave
Aiming Beam • Laser Type • Wavelength • Maximum Delivered Output Power	Diode 630-670 nm < 3 mW	Diode 632 nm <1 mW

The ECHOLASER X4 has the same indications for use as the abovementioned predicate device, with same principle of operation and essentially the same performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

The ECHOLASER X4 was tested for standards conformance with the following standards:

AAMI/ANSI ES60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility – Requirements and tests.

IEC 60601-2-22 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

IEC 60825-1- Safety of laser products – Part 1: Equipment classification and requirements.

Conclusion:

We can conclude that the ECHOLASER X4 laser system is substantially equivalent to the predicate device .

Additional Information:

None