April 26, 2021

EL.EN. Electronic Engineering Spa
Paolo Peruzzi
Regulatory Affair Manager
Via Baldanzese 17
Calenzano, FI 50041
Italy

Re: K202258
Trade/Device Name: ERISE Laser handpiece
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: March 17, 2021
Received: March 23, 2021

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 and Part 809); 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
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)*
K202258

Device Name
ERISE Laser Handpiece

Indications for Use *(Describe)*
ERISE Laser Handpiece is indicated for use in soft tissue (skin and cutaneous tissue) such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).
With microbeam end piece it is indicated for Skin resurfacing.

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

ERISE Laser Handpiece

Submitter:

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Contact:

Paolo Peruzzi

Regulatory Affairs Manager & Official Correspondent

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Date Summary Prepared:

April 15, 2021

Device Trade Name:

ERISE Laser handpiece

Common Name:

2940 nm Er:YAG laser handpiece

Classification:

Class II

Classification Name:

Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology

Product Code :

GEX

Classification Number:

21 CFR 878.4810

Predicate Device:

- K173002 – Quanta System 2940 nm Er:YAG laser handpiece

Device Description:

ERISE is an Erbium:YAG laser handpiece delivering laser radiation at 2940nm.

It is intended to be used with DEKA LUXEA platform, cleared by FDA with K192539.

The Erise laser handpiece includes:

- A connector to connect to the console
- A cord where electrical cables and hydraulic tubes pass in
- A plastic shell
- A Laser cavity
- A mechanical shutter
- An optical guide
- An ending tip which provides different spot sizes (diameter 2, 4, 9mm), including microbeam output (diameter 9mm)

The 2940 nm Erbium:YAG laser handpiece is controlled by the DEKA LUXEA console which it is connected to, through the connector.

Indications for Use:

ERISE Laser Handpiece is indicated for use in soft tissue (skin and cutaneous tissue) such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

With microbeam end piece it is indicated for Skin resurfacing.

Technological Characteristics Comparison:

ERISE laser handpiece is as safe, as effective, and performs as well as the legally marketed predicate device Quanta System 2940 nm Er:YAG laser handpiece (K173002):

	Proposed 510(k) Device	Predicate Device K173002
Device Trade Name	ERISE laser handpiece	Quanta System 2940 nm Er:YAG laser handpiece
Product code	GEX	GEX
Laser Wavelength	2940 nm	2940 nm
MAX Energy	3 J	3 J
MAX Fluence	Up to 95 J/cm2 (non microbeam mode); Up to 121 J/cm2 (with stacking pulses – microbeam mode)	Up to 95 J/cm2 (non microbeam mode); Up to 121 J/cm2 (with stacking pulses – microbeam mode)
Handpiece Spot Sizes	Ø 2, 4, 9mm Ø 9mm dots array	Ø 2, 4, 9mm Ø 9mm dots array
Pulse Duration	0.3 to 1.5 ms	0.3 to 1.5 ms
Pulse Repetition Rate	Up to 6 Hz	Up to 6 Hz
Diameter of the microbeams	300- 600 µm	300- 600 µm
Creation of microbeams	By microlenses array	By microlenses array
Number of dots	65-70	65-70
MAX Energy per Microbeam	180 mJ (stacking mode)	180 mJ (stacking mode)
Coverage of skin in microbeam mode	12%	12%

Clinical Performance Data:

None

Non-Clinical Performance Data:

The following performance data are provided in support of the substantial equivalence determination, for the ERISE laser handpiece used in conjunction with DEKA LUXEA platform.

Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the DEKA LUXEA platform.

The system complies with the IEC 60601-1, IEC 60601-2-22, IEC 60825-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software of DEKA LUXEA platform successfully underwent verification and validation testing including the use of ERISE Handpiece.

Software documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Conclusions:

Based on the comparison of indications for use and the technological characteristics, and on the outcome of non-clinical performance data provided , we can conclude that ERISE Laser handpiece is as safe, as effective, and performs as well as the legally marketed predicate device.

Additional Information:

None