October 21, 2021

EL.EN Electronic Engineering Spa
Paolo Peruzzi
Regulatory Affairs Manager
VIA Baldanzese 17
Calenzano, Firenze 50041
Italy

Re: K212270
Trade/Device Name: DEKA LipoAI
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: July 15, 2021
Received: July 20, 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)*
K212270

Device Name
DEKA LipoAI

Indications for Use *(Describe)*
The LipoAI is indicated for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The LipoAI is further indicated for laser assisted lipolysis.

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

DEKA LIPOAI

Submitter:

El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Contact:

Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
Phone: +39.055.8826807
E-mail: p.peruzzi@elen.it

Date Summary Prepared:

September 17, 2021

Device Trade Name:

DEKA LIPOAI

Common Name:

Powered Laser Surgical Instrument

Classification Name:

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

Product Code:

GEX

Regulatory Class:

Class II

Classification Number:

21 CFR 878.4810

Predicate Device:

Lutronic AccuSculpt II Laser system (K101573)

Device Description:

The LipoAI is medical laser equipped with a short pulse 1444 nm Nd:YAG laser source.

The device delivers the laser energy through a 600 um optical fiber. The fiber is protected by a small stainless-steel cannula (max. 1.4mm) and is inserted in the tissue through a small aperture in the skin.

The DEKA LipoAI device consists of:

- An AC/DC power supply unit
- CPU controller
- LASER source
- Cooling system
- User interface with LCD touch screen
- Beam delivery system

Laser activation is controlled by footswitch.

Electrical specifications are:

200-240V ~ single phase, 50/60 Hz, Absorbed electric power 3200 VA (max)

Indications for Use:

The LipoAI is indicated for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The LipoAI is further indicated for laser assisted lipolysis.

Comparison with The Predicate Device:

The DEKA LIPOAI is substantially equivalent to the AccuSculpt II Laser system (K101573):

Device Trade Name	Proposed Device **DEKA LipoAI**	Predicate Device **Lutronic AccuSculpt II** (K101573)	comment
Indications for Use	The LipoAI is indicated for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The LipoAI is further indicated for laser assisted lipolysis.	The AccuSculpt II Laser System is indicated for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The AccuSculpt II is further indicated for laser assisted lipolysis.	Identical
Regulation number	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology	Identical
Product Code	GEX	GEX	Identical
Laser type	• Pulsed Nd:YAG	• Pulsed Nd:YAG	Identical
Wavelength	1444 nm	1444 nm	Identical
Max Pulse Energy	300 mJ	300 mJ	Identical
Trasmission system	600 µm Optical fiber	600 µm Optical fiber	Identical
Pulse width	Up to 100 µs	Up to 100 µs	Identical

Device Trade Name	Proposed Device **DEKA LipoAI**	Predicate Device **Lutronic AccuSculpt II** (K101573)	comment
Pulse repetition rate	5-40 Hz	5-40 Hz	Identical
Aiming beam	Red and Green visible laser diode	Red visible laser diode	Difference does not affect safety and effectiveness of the device
Max Output power	12W	12 W	Identical

Clinical Performance Data:

None

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LipoAI device, according to the following standards:

- ANSI AAMI ES60601-1Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Software Validation and Verification Testing

Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Additional non-clinical testing conducted

Additional tests were conducted on the LipoAI device, according to the following standards:

- 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:

On the basis of the comparison with the predicate device and on the non-clinical performance data , we can conclude that DEKA LIPOAI is as safe, as effective, and performs as well as the legally marketed predicate device (K101573).

Additional Information:

None.