September 26, 2023

El.En. S.p.A
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, FI 50141
Italy

Re: K231971
Trade/Device Name: Deka Physiq 360
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: PKT
Dated: June 30, 2023
Received: July 3, 2023

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/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,

Tanisha L. Hithe -S
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Tanisha Hithe, MS, MHS
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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.

Submission Number *(if known)*

K231971

Device Name

DEKA PHYSIQ 360

Indications for Use *(Describe)*

The DEKA PHYSIQ 360 is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs, in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.

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 PHYSIQ 360

Submitter:

El.En. S.p.A.
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Contact:

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Regulatory Affairs Manager & Official Correspondent
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Date Summary Prepared:

June 30, 2023

Device Trade Name:

DEKA PHYSIQ 360

Common Name:

Laser for aesthetic use

Classification Name:

Laser for disruption of adipocyte cells for aesthetic use

Product Code:

PKT

Regulatory Class:

Class II

Classification Number:

21 CFR 878.5400

Predicate Device:

Sculpsure (K171992)

Device Description:

The PHYSIQ 360 is a diode laser device. The device is provided with:

- Up to 4 applicators that deliver the laser energy to the patient (to subcutaneous tissue layers).
- An LCD control panel with touch-screen technology provides information on the status and settings of the PHYSIQ 360 device to input commands into the system.
- One wavelength, 1060 ±20 nm (infrared)

The PHYSIQ 360 electrical specifications are: 115-230V~ single phase, 50/60Hz, 1200VA (max)

Indications for Use:

The PHYSIQ 360 device is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.

Comparison with The Predicate Device:

Device Trade Name	Proposed Device **DEKA PHYSIQ 360**	Predicate Device **Sculpsure** (K171992)	Comment
Indications for Use	The DEKA PHYSIQ 360 system is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs, in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.	The Cynosure SculpSure is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. In addition, the device is intended for non-invasive lipolysis of the submental area in individuals with a BMI of 43 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, thighs and submental area.	The proposed device's indications for use are a subset of the predicate's indications for use. The proposed and predicate devices' key technological parameters are the same, and thus the subset of the predicate device's indications for use are applicable to the proposed device
Regulation number	21 CFR 878.5400 Laser for disruption of adipocyte cells for aesthetic use	21 CFR 878.5400 Laser for disruption of adipocyte cells for aesthetic use	Identical
Product Code	PKT	PKT	Identical
Device Type	Diode Laser	Diode Laser	Identical
Lypolysis Method	Heat-assisted	Heat-assisted	Identical
Wavelength	1060 ±20 nm (infrared)	1060 ±20 nm (infrared)	Identical

Device Trade Name	Proposed Device **DEKA PHYSIQ 360**	Predicate Device **Sculpsure** (K171992)	Comment
Spot Size	4 x 6 cm on each of the applicator heads (up to four applicators per body treatment)	4 x 6 cm on each of the applicator heads (up to four applicators per body treatment) 14.28 cm2 (one applicator head and frame used for Submental treatment)	Identical for the proposed Indications for Use
Pulse Width (laser ON time)	CW	CW	Identical
Power Density	Up to 1.4 W/cm^2 (body)	Up to 1.4 W/cm^2 (body) Up to 2.35 W/cm^2 (submental)	Identical for the proposed Indications for Use
Attachment to patient	Belt (body treatment)	Belt (body treatment) Headgear and straps (submental treatment)	Identical for the proposed Indications for Use

Clinical Performance Data:

None

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the PHYSIQ 360 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, "Content of Premarket Submissions for Device Software Functions".

Additional non-clinical testing conducted

Additional tests were conducted on the PHYSIQ 360 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 PHYSIQ 360 is as safe, as effective, and performs as well as the legally marketed predicate device (K171992).

Additional Information:

None