May 16, 2024

El.EN S.p.A.
Paolo Peruzzi
Regulatory Affairs Manager
via Baldanzese 17
Calenzano, Fl 50041
Italy

Re: K233473
Trade/Device Name: Deka Lotus
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: ONF, GEI
Dated: April 18, 2024
Received: April 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Digitally signed by Tanisha L. Hithe -S
Date: 2024.05.16 12:27:47 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233473

Device Name

DEKA LOTUS

Indications for Use *(Describe)*

• The DEKA LOTUS 590nm pulsed light handpiece is indicated for permanent hair removal. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.
• The DEKA LOTUS 500G pulsed light handpiece is intended for treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait; and treatment of benign vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.
• The DEKA LOTUS RF handpiece is indicated for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

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 # K233473

DEKA LOTUS

Submitter:

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Contact:

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Date Summary Prepared:

April 18, 2024

Device Trade Name:

DEKA LOTUS

Common Name:

Medical Intense Pulsed Light and RF system.

Regulation Name:

Powered light-based non-laser surgical instrument with thermal effect, Electrosurgical cutting and coagulation device and accessories.

Product Code:

ONF, GEI

Regulatory Class:

Class II

Regulation Number:

21 CFR 878.4810
21 CFR. 878.4400

Predicate Devices:

Quanta Chrome (K202503)
Palomar Icon (K110907)
Pollogen Legend+™ System (K173503)

Device Description:

The DEKA Lotus is a device provided with two pulsed light handpieces and a RF handpiece.

The two pulsed light handpieces have a built-in cooled waveguide which differ in emission spectrum, connected to the main unit through a flexible multifunctional cable.
The handpiece uses a linear Xenon flashlamp, emitting a broad spectrum of electromagnetic radiation (light) when energized.
The RF handpiece produces a particular electric current at 1MHz that induces a molecular oscillation on the cells, raising their temperature locally. The RF current flows through the special electrodes, forming a homogeneous heat area.

Indications for Use:

The DEKA LOTUS 590 nm Pulsed Light handpiece is indicated for permanent hair removal. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.
The DEKA LOTUS 500G Pulsed Light handpiece is intended for treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait; and treatment of benign vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.
The DEKA LOTUS RF handpiece is intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Comparison with The Predicate Device:

The DEKA LOTUS is substantially equivalent to Quanta Chrome (K202503), Palomar Icon (K110907) AND Pollogen Legend+™ System (K173503):

590nm Pulsed light handpiece

Device Trade Name	Proposed 510(k) Device **DEKA LOTUS**	**Predicate Device K202503 QUANTA Chrome IPL 590-1200 nm**	Comments
Indications for Use	Indicated for permanent hair removal. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	Indicated for permanent hair removal. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	Identical
Product code and regulation	ONF 21 CFR 878.4810	GEX 21 CFR 878.4810	Predicate device includes laser handpiece while the subject device has only IPL.
Pulsed light Emission spectrum	590 - 1200 nm	590 - 1200 nm	Identical

Device Trade Name	Proposed 510(k) Device **DEKA LOTUS**	**Predicate Device** **K202503** **QUANTA Chrome** **IPL 590-1200 nm**	Comments
Fluence	Up to 25 J/cm^2	Up to 25 J/cm^2	Identical
Spot Size	20x17 mm	48x13 mm 25x13mm	Differences do not affect safety and effectiveness
Pulse Duration	Up to 40 ms	Up to 40 ms	Identical
Repetition Rate	3 Hz max.	3 Hz max.	Identical

500G Pulsed light handpiece

Device Trade Name	Proposed 510(k) Device **DEKA LOTUS**	Predicate Device **K110907** **Palomar Icon** **Max series Intense Pulsed light**	Comments
Indications for Use	Intended for treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait; and treatment of benign vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.	The Max Series Intense Pulsed Light Handpieces are intended for the treatment of inflammatory acne (acne vulgaris) and for the treatment of benign pigmented epidermal and cutaneous lesions, including warts, scars and striae; removal of unwanted hair from skin types 1-VI, and to effect stable long-term, or permanent, hair reduction; treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait; and treatment of vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.	Indications for use are a subset of the ones of the predicate device.
Product code and regulation	ONF 21 CFR 878.4810	GEX 21 CFR 878.4810	Predicate device includes laser handpiece while the subject device has only IPL.
Pulsed light Emission spectrum	500-670nm, 870-1200 nm	Max G handpiece: 500-670nm, 870-1200 nm	Identical
Fluence	Up to 80 J/cm^2	Up to 80 J/cm^2	Identical

Device Trade Name	Proposed 510(k) Device **DEKA LOTUS**	Predicate Device **K110907** **Palomar Icon** **Max series Intense Pulsed light**	Comments
Spot Size	17x20 mm	10x15 mm	Differences do not affect safety and effectiveness of the device
Pulse Duration	1-100 ms	1-100 ms	Identical
Repetition Rate	1 Hz max.	NA	NA

RF handpiece

Device Trade Name	Proposed 510(k) Device **DEKA LOTUS**	Predicate Device **K173503** **Pollogen Legend+™ System**	Comments
Indications for Use	Intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides	The Modified Pollogen Legend+™ system is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (Applicator VO). It is also intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar RF Energy (Applicators 1-3).	Indications for use are a subset of the ones of the predicate device. (No fractional Bipolar RF applicator available)
Product code and regulation	GEI 21 CFR. 878.4400	GEI 21 CFR 878.4400	Identical
Energy source	RF (bipolar)	RF (bipolar)	Identical
Frequency	1 MHz	1 MHz	Identical
Waveform	Sinusoidal	Sinusoidal	Identical
Applicator type	Bipolar RF, 3 electrodes	A2, A3: bipolar RF, 3 electrodes A1: bipolar RF, 6 electrodes, VO: fractional bipolar RF	Subset (no fractional bipolar RF or bipolar RF with 6 electrodes available).
Maximum output power	50W on 200Ohm (large tip) 15W on 200Ohm (medium tip)	50W on 200Ohm (applicatorA2) 15W on 200Ohm (applicator A3)	Identical

Device Trade Name	Proposed 510(k) Device **DEKA LOTUS**	Predicate Device **K173503** **Pollogen Legend+™ System**	Comments
Output voltage on 200Ohm	100V rms	100V rms	Identical
Power delivery algorithms	Power regulation by PWM modulation, phase rotation between electrodes	Power regulation by PWM modulation, phase rotation between electrodes	Identical
Electrodes diameter	15 mm (large tip) 6 mm (medium tip)	15 mm (Applicator A2) 6 mm (Applicator A3)	Identical
Electrodes height	15 mm (large tip) 14 mm (medium tip)	15 mm (Applicator A2) 14 mm (Applicator A3)	Identical
Distance between electrodes centers	20 mm (large tip) 10 mm (medium tip)	20 mm (Applicator A2) 10 mm (Applicator A3)	Identical

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 ES60601-1: 2005 / A1: 2012 / A2: 2020: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2014 / A1: 2020: 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 LOTUS device:

- Test according to IEC 60601-2-57 Edition 1.0 2011-01: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

- Test according to the standard IEC 60601-2-57 Edition 1.0 2011-01:

- side-by-side electrical comparison between RF handpiece and predicate device (K173503)
- side-by-side thermal profile comparison between RF handpiece and predicate device (K173503)

Conclusion:

Based on the comparison of indications for use and the technological characteristics, we can conclude that the DEKA LOTUS device is as safe, as effective, and performs as well as the legally marketed predicate devices K202503, K110907 and K173503.

Additional Information:

None.