El..EN. Electronic Engineering SPA
Paolo Peruzzi
Regulatory Affairs Manager
via Baldanzese 17
Calenzano, 50041 It

December 16, 2019

Re: K192539
Trade/Device Name: Deka Luxea
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, ONF
Dated: September 12, 2019
Received: September 16, 2019

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,

Neil R.P. Ogden, MS
Assistant Director THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192539

Device Name
DEKA LUXEA

Indications for Use *(Describe)*

VIVID LASER handpiece:
Indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction.

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

SPARKS LASER handpiece :
Indicated for removal of unwanted hair, for stable long term or permanent hair reduction (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of benign pigmented and vascular lesions, such as but not limited to warts, teleangiectasia, leg veins and spider veins, treatment of benign pigmented lesions.

PRISMA LASER handpiece:
Indicated for removal of dark tattoos and treatment of benign pigmented lesions.

RUBER, LILAC Pulsed Light handpieces:
Permanent hair reduction. photocoagulation of benign vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.

Different wavelength ranges of Pulsed Light attachment are indicated for the various treatments and skin types. as indicated in the following table:

Pulsed light Wavelength range	Hair reduction	Benign Vascular lesions	Blood vessels	Benign Pigmented lesions
500-1200nm	-	Skin Types I, II	Skin Types I, II	-
520-1200nm	-	SkinType Ill	Skin Type III	Skin Types I, II
550-1200nm	Skin Types I, II	-	-	Skin Type Ill
600-1200nm	Skin Type Ill	-	-	-
650-1200nm	Skin Type IV	-	-	Skin Type IV

LAZUR Pulsed Light handpiece:
The handpiece (with and without contact-cooling) is indicated for:
-The treatment of moderate inflammatory acne vulgaris.
-The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
-The treatment of benign cutaneous lesions including warts, scars and striae.
-The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea,
angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- Use on all skin types (Fitzpatrick I-VI).

VIRIDIS Pulsed Light handpiece:
Photocoagulation of benign dermatological vascular lesions, photothermolysis of blood vessels (treatment of facial and-leg veins), and the treatment of benign pigmented lesions.

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

DEKA LUXEA

Submitter:

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Date Summary Prepared:

December 11, 2019

Device Trade Name:

DEKA LUXEA

Common Name:

Medical Laser and pulsed Light platform

Classification Name:

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

Product Code :

GEX, ONF

Classification Number:

21 CFR 878.4810

Equivalent Devices:

- K152714 – Quanta Forte
- K103288 – DEKA Synchro FT
- K142860 – Lumenis M22
- K150516 – DEKA Synchro Replay
- K072564 – Alma Laser Harmony XLTm Multi-Application Platform
- K020941 – Palomar LuxG

Device Description:

The DEKA LUXEA is a versatile medical platform that can be equipped with various types of laser and pulsed light handpieces.
Thanks to its universal connector it is possible to quickly insert and deactivate the various handpieces to cover a wide spectrum of application.

The available handpieces are

- VIVID: 808±10 nm Laser
- SPARKS: 1064nm Laser
- PRISMA: 1064nm Q-Switched laser
- VIRIDIS: Pulsed Light handpiece 15mmx13mm with integrated 500-1200 nm filter
- LILAC: Pulsed Light handpiece 48mmx13mm with interchangeable filters
- RUBER: Pulsed Light handpiece 48mmx17mm with integrated 550nm filter
- LAZUR: Pulsed Light handpiece 48mmx13mm with integrated 420-950 nm filter

Emission activation is either by footswitch or fingerswitch.
Electrical specifications are 115-240V~, 50-60Hz, 2300VA max.

Indications for Use:

VIVID LASER handpiece:

Indicated for the treatment of benign vascular lesions, benign pigmented lesions, hair removal and permanent hair reduction.

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.

SPARKS LASER handpiece :

Indicated for removal of unwanted hair, for stable long term or permanent hair reduction (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of benign pigmented and vascular lesions, such as but not limited to warts, teleangiectasia, leg veins and spider veins, treatment of benign pigmented lesions.

PRISMA LASER handpiece:

Indicated for removal of dark tattoos and treatment of benign pigmented lesions

RUBER, LILAC Pulsed Light handpieces:

Permanent hair reduction. photocoagulation of benign vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.

Different wavelength ranges of Pulsed Light attachment are indicated for the various treatments and skin types. as indicated in the following table:

Pulsed light Wavelength range	Hair reduction	Benign Vascular lesions	Blood vessels	Benign Pigmented lesions
500-1200nm	-	Skin Types I, II	Skin Types I, II	-
520-1200nm	-	Skin Type III	Skin Type III	Skin Types I, II
550-1200nm	Skin Types I, II	-	-	Skin Type III
600-1200nm	Skin Type III	-	-	-
650-1200nm	Skin Type IV	-	-	Skin Type IV

LAZUR Pulsed Light handpiece:

The handpiece (with and without contact-cooling) is indicated for:

-The treatment of moderate inflammatory acne vulgaris.

-The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).

-The treatment of benign cutaneous lesions including warts, scars and striae.

-The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

- Use on all skin types (Fitzpatrick I-VI).

VIRIDIS Pulsed Light handpiece:

Photocoagulation of benign dermatological vascular lesions, photothermolysis of blood vessels (treatment of facial and-leg veins), and the treatment of benign pigmented lesions.

Substantial equivalence discussion:

The VIVID Laser Handpiece is substantially equivalent to the Quanta Forte 808nm laser (cleared with K152714):

Device Trade Name	**DEKA LUXEA VIVID LASER handpiece**	Predicate Device **K152714 Quanta Forte**
Product code and regulation	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810
Laser Wavelength	808±10 nm	808±10 nm
MAX Fluence	40 J\cm2	44 J/cm²
Handpiece Spot Sizes	10x12 mm	12 x 14 mm
Pulse Duration	Up to 200ms	Up to 200ms
Pulse Repetition Rate (Hz)	Single shot to 10 Hz	Single shot to 10 Hz

The SPARKS Laser Handpiece is substantially equivalent to the DEKA Synchro FT (cleared with K103288):

Device Trade Name	**DEKA LUXEA SPARKS LASER handpiece**	Predicate Device **K103288 DEKA Synchro FT**
Product code and regulation	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810
Laser Wavelength	1064 nm	1064 nm
MAX Fluence	80-700 J/cm^2 (2.5 mm) 30-250 J/cm^2 (4 mm) 14-170 J/cm^2 (6 mm) 5-60 J/cm^2 (10 mm)	70-700J/cm^2 (2.5mm) 30 243J/cm^2 (5mm) 25-124J/cm^2 (7mm) 20 60J/cm^2 (10mm) 15 36J/cm^2 (13mm) 10 25J/cm^2 (16mm)
Handpiece Spot Sizes	Ø 2.5, 4, 6, 10 mm	Ø 2.5, 5, 7, 10, 13, 16 mm
Pulse Duration	1- 280 ms	0.8 – 285 ms
Pulse Repetition Rate	Single shot to 10 Hz	0.5 to 10 Hz

The PRISMA Laser Handpiece is substantially equivalent to the Lumenis M22 (cleared with K142860):

Device Trade Name	Proposed 510(k) Device **DEKA LUXEA** **PRISMA LASER handpiece**	Predicate Device **K142860** **Lumenis M22**
Product code and regulation	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810
Laser Wavelength	1064nm	1064nm
MAX Fluence	14 J/cm^2 (2.5x2.5mm) 9 J/cm^2 (3x3mm)	14 J/cm^2
Handpiece Spot Sizes	2.5x2.5 mm 3x3 mm	Ø 2-8 mm
Pulse Duration	6ns	6-8 ns
Pulse Repetition Rate	1 to 5 Hz	5Hz

The RUBER and LILAC Pulsed light Handpieces are substantially equivalent to the DEKA Synchro Replay FT Pulsed light handpiece (cleared with K150516):

Device Trade Name	**DEKA LUXEA** **RUBER, LILAC Pulsed Light handpieces**	Predicate Device **K150516** **DEKA Synchro Replay**
Product code and regulation	ONF 21 CFR 878.4810	ONF 21 CFR 878.4810
Pulsed light Emission spectrum	500 - l200nm (LILAC) 520 - l200nm (LILAC) 550 - l200nm (RUBER, LILAC) 600 - l200nm (LILAC) 650 - l200nm (LILAC)	500 - l200nm 520 - l200nm 550 - l200nm 600 - l200nm 650 - l200nm
Fluence	1 - 25 J/cm^2 (LILAC) 1 - 20 J/cm^2 (RUBER)	3 - 25 J/cm^2
Spot Sizes	48x13 mm (LILAC) 48x17 mm (RUBER)	48x13 mm
Pulse Duration	3 – 124 ms (LILAC) 8 – 50 ms (RUBER)	3 – 124 ms
Repetition Rate	0.5 Hz max.	0.5 Hz max.
Method of Skin Cooling	Integrated - provided via the handpiece lightguide	Integrated - provided via the handpiece lightguide

The LAZUR Pulsed light Handpiece is substantially equivalent to the Alma Laser Harmony XLTm Multi-Application Platform (cleared with K072564):

Device Trade name	Proposed 510(k) Device **DEKA LUXEA** **LAZUR Pulsed Light handpiece**	Predicate Device **K072564** **ALMA LASER Harmony XLTm Multi-Application Platform**
Product code and regulation	ONF 21 CFR 878.4810	ONF 21 CFR 878.4810
Pulsed light Emission spectrum	420-950 nm	420 -950 nm
Fluence	3 - 20 J/cm^2	5 – 25 J/cm^2
Spot Sizes	6.2 cm^2 (48 mm x 13 mm)	6.4 cm^2
Pulse Duration	30, 40, 50 ms	30, 40, 50 ms
Repetition Rate	0.5 Hz max	0.5 Hz
Method of Skin Cooling	Optional , integrated, provided via the handpiece lightguide	Optional

The VIRIDIS Pulsed light Handpiece is substantially equivalent to the Palomar LuxG (cleared with K020941):

Device Trade Name	Proposed 510(k) Device **DEKA LUXEA** **VIRIDIS Pulsed light handpiece**	Predicate Device **K020941** **Palomar LuxG**
Product code and regulation	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810
Pulsed light Emission spectrum	500 -677 & 854 l200nm	500 – 670 & 870 -l400nm
Fluence	up to 50 J/cm^2	up to 50 J/cm^2
Spot Sizes	15x13 mm	15x10 mm
Pulse Duration	3 – 116 ms	1 – 100 ms
Repetition Rate	1 Hz max.	2 Hz max.
Method of Skin Cooling	Integrated - provided via the handpiece lightguide	Integrated - provided via the handpiece lightguide

The DEKA LUXEA laser and pulsed light handpieces have the same indications for use as the abovementioned predicate devices, with same principle of operation and essentially the same performances.

Clinical Performance Data:

None.

Non-Clinical Performance Data:

The LUXEA was tested for conformance with the following standards:

IEC 60601-1- 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.

IEC 60601-2-57 - Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Conclusion:

We can conclude that the DEKA LUXEA laser system is substantially equivalent to the predicate devices .

Additional Information:

None.