August 30, 2018

Elen Electronic Engineering Spa
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese, 17
Calenzano, 50041 IT FI

Re: K181486
Trade/Device Name: DEKA MOTUS AY
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: May 31, 2018
Received: June 6, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K181486

Device Name
DEKA MOTUS AY

Indications for Use *(Describe)*
Alexandrite 755nm laser source:
Temporary hair reduction.
Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. 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, on all skin types (Fitzpatrick I – VI) including tanned skin.
Treatment of benign pigmented lesions.
Treatment of wrinkles.
Photocoagulation of benign dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Nd:YAG 1064nm laser source:
Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB . The lasers are indicated on all Skin Types Fitzpatrick I-VI including tanned skin.
Photocoagulation and hemostasis of benign pigmented and benign vascular lesions, such as but not limited to port wine stains, hemangioma, warts, teleangiectasia, rosacea, venus lake, leg veins and spider veins.
Coagulation and hemostasis of soft tissue.
Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.
The laser is indicated for benign pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
Treatment of wrinkles.

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 Motus AY

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:

August 28, 2018

Device Trade Name:

DEKA MOTUS AY

Common Name:

Medical Laser system

Classification Name:

Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (GEX)

Classification Number:

21 CFR 878.4810

Predicate Devices:

Primary predicate: Synchro Repla:Y family of laser systems (K150516).
Reference predicate: DEKA Motus AX (K162886)

Device Description:

The DEKA MOTUS AY is a medical device equipped with two laser sources: 755nm and 1064nm. The laser sources deliver the laser output through a lens coupled user replaceable optical fiber with a wide range of interchangeable, quick release laser handpieces with electronic spot recognition. Handpiece activation is either by footswitch or fingerswitch.

Intended Use:

Alexandrite 755nm laser source:

Temporary hair reduction.
Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. 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, on all skin types (Fitzpatrick I – VI) including tanned skin.
Treatment of benign pigmented lesions.
Treatment of wrinkles.
Photocoagulation of benign dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Nd:YAG 1064nm laser source:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB . The lasers are indicated on all Skin Types Fitzpatrick I-VI including tanned skin.
Photocoagulation and hemostasis of benign pigmented and benign vascular lesions, such as but not limited to port wine stains, hemangioma, warts, teleangiectasia, rosacea, venus lake, leg veins and spider veins.
Coagulation and hemostasis of soft tissue.
Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.
The laser is indicated for benign pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
Treatment of wrinkles.

Substantial equivalence discussion:

The DEKA MOTUS AY is substantially equivalent to the DEKA Synchro Repla:Y family of laser systems (K150516).

755 nm laser:

Device Trade Name	Proposed 510(k) Device DEKA MOTUS AY	Predicate Device K162886 DEKA Motus AX	Predicate Device K150516 DEKA Synchro Repla:Y family of laser systems
Laser Type	Alexandrite	Alexandrite	Alexandrite
Wavelength (nm)	755 nm	755 nm	755 nm
MAX Fluence (J/cm^2)	2-200 J/cm^2	2-600 J/cm^2	2-600 J/cm^2
Handpiece Spot Sizes (diameter millimeter)	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20 mm	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20 mm	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20, 22, 24 mm
Pulse Duration (milliseconds)	2 to 50 ms	2 to 50 ms	0.2 to 50 ms
Pulse Repetition Rate (Hz)	up to 10 Hz	up to 10 Hz	up to 10 Hz

Device Trade Name	Proposed 510(k) Device DEKA MOTUS AY	Predicate Device K162886 DEKA Motus AX	Predicate Device K150516 DEKA Synchro Repla:Y family of laser systems
Skin Cooling System	Yes (handpiece integrated and external)	Yes (handpiece integrated and external)	Yes (handpiece integrated and external)
Skin Cooling temperature	15°C	15°C	4-20°C

1064 nm laser:

Device Trade Name	Proposed 510(k) Device DEKA MOTUS AY	Predicate Device K150516 DEKA Synchro Repla:Y family of laser systems
Laser Type	Nd:YAG	Nd:YAG
Wavelength (nm)	1064 nm	1064 nm
MAX Fluence (J/cm^2)	2-600 J/cm^2	2-600 J/cm^2
Handpiece Spot Sizes (diameter millimeter)	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20 , mm	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20, 22, 24 mm
Pulse Duration (milliseconds)	0.2 to 50 ms	0.2 to 50 ms
Pulse Repetition Rate (Hz)	up to 10 Hz	up to 10 Hz
Skin Cooling System	Yes (handpiece integrated and external)	Yes (handpiece integrated and external)
Skin Cooling temperature	15°C	4-20°C

The DEKA MOTUS AY has the same indications for use as the above mentioned predicate devices, with same principle of operation and essentially the same performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

The DEKA MOTUS AY was tested for standards conformance with the following standards:

AAMI/ANSI ES60601-1- Medical 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.

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:

Based on the outcome of non-clinical performance data performed, we can conclude that the DEKA Motus AY laser system is substantially equivalent to the predicate devices .

Additional Information:

None