DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 19, 2017

El.En. Electronic Engineering Spa
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
50041 Calenzano (FI), Italy

Re: K162886
Trade/Device Name: DEKA Motus AX
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 15, 2017
Received: May 18, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162886

Device Name
DEKA Motus AX

Indications for Use *(Describe)*

The DEKA Motus AX laser system is indicated for:

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).

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 AX

Submitter:

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Contact:

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Date Summary Prepared:

June 19th, 2017

Device Trade Name:

DEKA Motus AX

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:

DEKA Synchro Repla:Y family of laser systems (K150516).

Device Description:

The DEKA Motus AX is a medical device equipped with a 755nm solid state laser source.
The laser source delivers 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:

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).

Substantial equivalence discussion:

The DEKA Motus AX is substantially equivalent to the 755nm laser source of the DEKA Synchro Repla:Y family of laser systems (K150516).

Device Trade Name	**DEKA Motus AX**	Predicate Device **K150516** **DEKA Synchro Repla:Y family of laser systems** (755nm laser source)
Laser Type	Alexandrite	Alexandrite
Wavelength	755 nm	755 nm
Max Fluence	2.5mm handpicece: 600J/cm2 5mm handpicece: 160J/cm2 7mm handpicece: 80J/cm2 10mm handpicece: 40J/cm2 12mm handpicece: 27J/cm2 14mm handpicece: 20J/cm2 15mm handpicece: 17J/cm2 16mm handpicece: 15J/cm2 18mm handpicece: 12J/cm2 20mm handpicece: 10J/cm2 Mŏveō handpicece:8J/cm2	2.5mm handpicece: 600J/cm2 5mm handpicece: 160J/cm2 7mm handpicece: 80J/cm2 10mm handpicece: 40J/cm2 12mm handpicece: 27J/cm2 14mm handpicece: 20J/cm2 15mm handpicece: 17J/cm2 16mm handpicece: 15J/cm2 18mm handpicece: 12J/cm2 20mm handpicece: 10J/cm2 22mm handpicece: 16J/cm2 24mm handpicece: 14J/cm2
Spot Sizes	2.5 to 20mm	2.5 to 24mm
Pulse Duration	0.25 to 300 ms	0.25 to 300 ms
Pulse Rep Rate	up to 10 Hz	up to 10 Hz
Skin Cooling System	Yes, integrated in the Moveo handpiece, external optional for the other handpieces	Yes, optional, integrated by Smartcooler handpiece or external.

The DEKA Motus AX has the same indications for use as the above mentioned predicate device, with same principle of operation and essentially the same performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

The DEKA Motus AX was tested for standards 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.

Moreover, ex-vivo performance data on three different tissue types were submitted in order to show that DEKA Motus AX produces comparable thermal energy distribution and adversely affected tissue region as the predicate for the range of energy deposition parameters from the subject and predicate devices for the worst-case deposition time.

Finally, biocompatibility tests have been performed on the Moveo handpiece tip, which comes in contact with the patient.

Conclusion:

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

Additional Information:

None