July 6, 2021

El.En Electronic Engineering SPA
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, Florence 50041
Italy

Re: K211821
Trade/Device Name: DEKA Motus AZ
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: June 8, 2021
Received: June 11, 2021

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 and Part 809); 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,

Purva Pandya
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211821

Device Name
DEKA Motus AZ

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 AZ – Special 510(k)

Submitter:

El.En. S.p.A.
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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:

June 25, 2021

Device Trade Name:

DEKA Motus AZ

Common Name:

Powered Laser Surgical Instrument

Classification Name:

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

Product Code:

GEX

Regulatory Class:

Class II

Classification Number:

21 CFR 878.4810

Predicate Device:

DEKA MOTUS AY (K181486)

Device Description:

Motus AZ is a medical device equipped with Alexandrite 755nm laser and Nd:YAG 1064nm laser.

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.

The modifications to the device consist on a restyling of the device (chassis, cover plastics and GUI) and on modifications to Moveo handpiece (new spot sizes available and new optional spacer). The spot size and the fluences are within the range of the already cleared device (K181486). The optional spacer is made of a biocompatible material (Anticorodal 6082), already used in previously cleared devices for the same type of contact (K192539, K172363, K172362, K133895).

The intended use of the modified devices, as described in the labelling, has not changed as a result of the modifications. Labelling itself has been updated also to include general improvements that have been implemented since predicate device clearance and considered as minor changes.

Indications for 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.

Comparison With The Predicate Device:

GENERAL SPECIFICATIONS

Device Trade Name	Proposed Device **DEKA Motus AZ**	Predicate Device **DEKA MOTUS AY** (K181486)	Comment
Weight	Approx. 100 kg	Approx. 90 kg	The variation to the weight does not affect safety and effectiveness of the device
Dimensions (cm)	114x45x94 (HxWxD)	95x51x83 (HxWxD)	The variation to the dimensions does not affect safety and effectiveness of the device
Mains voltage	230 V~single phase, 50-60 Hz	230 V~single phase, 50-60 Hz	Identical
Breaker	16 A	16 A	Identical
Operating environmental conditions	15-35 °C; 30%-75% rel. humidity, 700-1060 hPa	15-35 °C; 30%-75% rel. humidity, 700-1060 hPa	Identical
Transport and storage conditions	5-50 °C; 10-90% humidity, 700-1060 hPa	5-50 °C; 10-90% humidity, 700-1060 hPa	Identical

755 nm LASER

Device Trade Name	Proposed Device **DEKA Motus AZ**	Predicate Device **DEKA MOTUS AY** (K181486)	Comment
Indications for 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).	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).	Identical
Regulation number	21 CFR 878.4810: Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 878.4810: Laser surgical instrument for use in general and plastic surgery and in dermatology	Identical
Product Code	GEX	GEX	Identical

Device Trade Name	Proposed Device **DEKA Motus AZ**	Predicate Device **DEKA MOTUS AY** (K181486)	Comment
Laser Type	Alexandrite	Alexandrite	Identical
Wavelength (nm)	755 nm	755 nm	Identical
Fluence (J/cm^2)	2-200 J/cm^2	2-200 J/cm^2	Identical
Handpiece Spot Sizes (diameter millimeter)	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20 mm (Moveo: 7, 14 mm)	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20 mm (Moveo: 14 mm)	Identical overall spot size range
Pulse Duration (milliseconds)	2 to 50 ms	2 to 50 ms	Identical
Pulse Repetition Rate (Hz)	up to 10 Hz	up to 10 Hz	Identical
Skin Cooling System	Yes (handpiece integrated and external)	Yes (handpiece integrated and external)	Identical
Skin Cooling Temperature	15°C	15°C	Identical

1064 nm LASER

Device Trade Name	Proposed Device **DEKA Motus AZ**	Predicate Device **DEKA MOTUS AY (K181486)**	Comment
Indications for Use	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	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	Identical

Device Trade Name	Proposed Device **DEKA Motus AZ**	Predicate Device **DEKA MOTUS AY (K181486)**	Comment
	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.	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.	
Regulation number	21 CFR 878.4810: Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 878.4810: Laser surgical instrument for use in general and plastic surgery and in dermatology	Identical
Product Code	GEX	GEX	Identical
Laser Type	Nd:YAG	Nd:YAG	Identical
Wavelength (nm)	1064 nm	1064 nm	Identical
Fluence (J/cm^2)	2-600 J/cm2	2-600 J/cm2	Identical

Device Trade Name	Proposed Device **DEKA Motus AZ**	Predicate Device **DEKA MOTUS AY (K181486)**	Comment
Handpiece Spot Sizes (diameter millimeter)	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20 mm (Moveo: 5, 14 mm)	2.5, 5, 7, 10, 12, 14, 15, 16, 18, 20 mm (Moveo: 14 mm)	Identical overall spot size range
Pulse Duration (milliseconds)	0.2 to 50 ms	0.2 to 50 ms	Identical
Pulse Repetition Rate (Hz)	up to 10 Hz	up to 10 Hz	Identical
Skin Cooling System	Yes (handpiece integrated and external)	Yes (handpiece integrated and external)	Identical
Skin Cooling Temperature	15°C	15°C	Identical

Performance data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Motus AZ 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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Additional non-clinical testing conducted

Additional tests were conducted on the Motus AZ 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:

Based on the comparison of indications for use and the technological characteristics, we can conclude that DEKA Motus AZ is as safe, as effective, and performs as well as the legally marketed predicate device (K181486).

Additional Information:

None.