June 21, 2024

El.En. S.p.A.
Peruzzi Paolo
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, FI 50041
Italy

Re: K241459
Trade/Device Name: MOTUS PRO Family
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 20, 2024
Received: May 23, 2024

Dear Peruzzi Paolo:

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,

Yan Fu -S
Digitally signed by Yan Fu -S
Date: 2024.06.21 14:59:07 -04'00'

for

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241459

Device Name

MOTUS PRO Family

Indications for Use *(Describe)*

MOTUS PRO family is a medical laser family intended for:

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) included tanned skin.
- Treatment of benign pigmented lesions.
- 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 laser are indicated on all Skin Types Fitzpatrick I-VI including tanned skin.
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to, port wine stains, hemangioma, warts, teleangiectasias, 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), cafè 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 patient with lesions that have not responded to other 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.

510(k) Summary K241459

MOTUS PRO family – Special 510(k)

Submitter:
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50041 Calenzano (FI), Italy

Contact:
Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
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Data Summary Prepared:
May 20, 2024

Device Trade Name:
MOTUS PRO family

Manufacturer:
DEKA M.E.L.A. srl
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Common Name:
Medical laser system

Regulation Number:
21 CFR 878.4810

Regulation Name:
Laser Surgical Instrument for use in General and Plastic and in Dermatology

Regulation Class:
Class II

Product Code:
GEX

Predicate Devices:
Primary predicate: DEKA Motus AZ (K211821)
Reference predicate: DEKA AGAIN PRO family (K233090)

Device Description:

MOTUS PRO family is a medical laser family 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 device available with Alexandrite source only has the brand name MOTUS PRO AX.

The modifications to the device respect to DEKA Motus AZ (K211821) consist of a restyling of the device (chassis, cover plastic and GUI) and on modification to spot size ranges (new spot size available), pulse duration, 755nm maximum fluence and maximum pulse repetition rate. The modified specifications are within the range of the already cleared reference device (K233090).

The intended use of modified device, 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 clearance of predicate device and reference device and considered as minor changes.

Indications for Use:

The MOTUS PRO family is a medical device laser family intended for:

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.
- Photocoaugulation 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), café 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 equivalent discussion:

Device Trade Name	Subject Device **MOTUS PRO family**	Predicate Device **K211821** **MOTUS AZ**	Reference Device **K233090** **AGAIN PRO FAMILY**	Comment
755 nm LASER				
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. Photocoaugulation 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 compilation of a treatment regime, on all skin types (Fitzpatrick I-VI) including tanned skin. Treatment of benign pigmented lesions. Photocoaugulation 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) included tanned skin. Treatment of benign pigmented lesions. Treatment of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).	Identical
Regulation number	21 CFR 8784810: Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 8784810: Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 8784810: Laser surgical instrument for use in general and plastic surgery and in dermatology	Identical
Product code	GEX	GEX	GEX	Identical

Device Trade Name	Subject Device **MOTUS PRO family**	Predicate Device **K211821** **MOTUS AZ**	Reference Device **K233090** **AGAIN PRO FAMILY**	Comment
Wavelength	755nm	755nm	755nm	Identical
Max Fluence	Stamp handpieces: 600 J/cm^2 Moveo handpieces: 40 J/cm^2	Stamp handpieces: 200 J/cm^2 Moveo handpieces: 40 J/cm^2	Stamp handpieces: 600 J/cm^2	Identical to reference for stamp handpieces. Identical to predicate for Moveo handpieces
Handpiece Spot Sizes (diameter)	Stamp handpieces: 2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm 22 mm 24 mm Moveo handpieces: 7 mm 14 mm	Stamp handpieces: 2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm Moveo handpieces: 7 mm 14 mm	Stamp handpieces: 2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm 24 mm 30 mm	Within the range of reference device for stamp handpieces. Identical to predicate for Moveo handpieces.

Device Trade Name	Subject Device **MOTUS PRO family**	Predicate Device **K211821** **MOTUS AZ**	Reference Device **K233090** **AGAIN PRO FAMILY**	Comment
Pulse Duration	0.2 to 300 ms	2 to 50 ms (single) 14 to 300 ms (burst)	0.2 to 300 ms	Identical to reference
Pulse Repetition Rate	Up to 12 Hz	Up to 10 Hz	Up to 12 Hz	Identical to reference
Skin Cooling System	Yes, optional	Yes, optional	Yes, optional	Identical
Skin Cooling Temperature	15°C	15°C	-	Identical to predicate
1064 nm LASER (not available for Motus PRO AX)				
Indication 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), café au lait	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), café au lait	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 hemostatis of pigmented and 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), café au lait	Identical

Device Trade Name	Subject Device **MOTUS PRO family**	Predicate Device **K211821** **MOTUS AZ**	Reference Device **K233090** **AGAIN PRO FAMILY**	Comment
	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.	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.	macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques. 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 treatment. 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 8784810: Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 8784810: Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 8784810: Laser surgical instrument for use in general and plastic surgery and in dermatology	Identical
Product code	GEX	GEX	GEX	Identical
Wavelength	1064 nm	1064 nm	1064 nm	Identical
Max Fluence	Stamp handpieces: 600 J/cm^2 Moveo handpieces: 50 J/cm^2	Stamp handpieces: 600 J/cm^2 Moveo handpieces: 50 J/cm^2	Stamp handpieces: 600 J/cm^2	Identical to predicate.

Device Trade Name	Subject Device **MOTUS PRO family**	Predicate Device **K211821** **MOTUS AZ**	Reference Device **K233090** **AGAIN PRO FAMILY**	Comment
Handpiece Spot Sizes (diameter)	<u>Stamp handpieces</u>: 2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm 22 mm 24 mm <u>Moveo handpieces</u>: 5 mm 14 mm	<u>Stamp handpieces</u>: 2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm <u>Moveo handpieces</u>: 5 mm 14 mm	<u>Stamp handpieces</u>: 2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm 22 mm 24 mm 30 mm	Within the range of reference device for stamp handpieces. Identical to predicate for Moveo handpieces.
Pulse Duration	0.2 to 300 ms	2 to 300 ms	0.2 to 300 ms	Identical to reference
Pulse Repetition Rate	Up to 12 Hz	Up to 10 Hz	Up to 12 Hz	Identical to reference
Skin Cooling System	Yes, optional	Yes, optional	Yes, optional	Identical
Skin Cooling Temperature	15°C	15°C	-	Identical to predicate

The MOTUS PRO family is substantially equivalent to a legally marketed devices DEKA Motus AZ (K211821) and DEKA AGAIN PRO family (K233090).

Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the MOTUS PRO family device, according to 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 2-2: 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.

Software Validation and Verification Testing

Software verification and validation testing were conducted and documented as a recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submission for Device Software Functions".

Conclusion:

Based on the comparison of indication for use and the technological characteristics, we can conclude that MOTUS PRO family device is safe, as effective, and performs as well as the legally marketed predicate device (K211821) and reference device (K233090).

Additional Information:

None