October 27, 2023

El. En. S.p.A.
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, Fl 50141
Italy

Re: K233090
Trade/Device Name: DEKA AGAIN 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: September 26, 2023
Received: September 26, 2023

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 (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,

Tanisha L. Hithe -S

Tanisha L. Hithe -S
2023.10.27
00:30:55 -04'00'

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233090

Device Name

DEKA AGAIN PRO family

Indications for Use *(Describe)*

The DEKA AGAIN PRO family is a medical laser family intended for:

Alexandrite laser (755nm):
- 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).

Nd:YAG laser (1064nm):
- 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 Fitzapatrick I-VI including tanned skin.
- Photocoagulation and hemostasis 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 od soft tissue.
- Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (such spots), cafè au lait 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 treatments.
- 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K233090

AGAIN PRO family – 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:
October 20, 2023

Device Trade Name:
DEKA AGAIN PRO

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

Regulatory Class:
Class II

Product Code:
GEX

Predicate Devices:

DEKA SYNCHRO REPLA:Y family of Laser system (K150516)

Device Description:

The DEKA AGAIN 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 wider range of interchangeable, quick release laser handpieces with electronic spot recognition.

The modifications to the device consist in a restyling of the device (new chassis, cover plastic, dimensions, weight and GUI, removal of Pulsed Light FT handpiece) and in modification to spot size ranges (new spot size available).

The intended use of the 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 predicate device clearance and considered as minor changes.

Intended Use:

The DEKA AGAIN PRO family is 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.
  Treatment of wrinkles.
  Photocoagulation of 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 is indicated on all Skin Types Fitzpatrick I-VI including tanned skin.
  Photocoagulation and hemastatis 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), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.
The laser is indicated for pigmented lesions to reduce lesion size, or 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 in an integral part of the scar.
Treatment of wrinkles.

Substantial equivalence discussion:

Device Trade Name	Subject Device **AGAIN PRO family**	Predicate Device **K150516** **SYNCHRO REPLA:Y**	Comment
Indications for use	Alexandrite 755 nm laser: 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. Treatment of benign pigmented lesions. Treatment of wrinkles. Photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias). Nd:YAG 1064 nm laser: 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 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 macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques. The laser is indicated for pigmented lesions to reduce lesion	Alexandrite 755 nm laser: 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. Treatment of benign pigmented lesions. Treatment of wrinkles. Photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias). Nd:YAG 1064 nm laser: 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 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 macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.	Identical for 755nm laser and 1064nm laser; Pulsed light FT handpiece is not available for Again Pro Family

<table>
<tr><th>Device Trade Name</th><th>Subject Device
AGAIN PRO family</th><th>Predicate Device
K150516
SYNCHRO REPLA:Y</th><th>Comment</th></tr>
<tr><td></td><td>size, or 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.</td><td>The laser is indicated for pigmented lesions to reduce lesion size, or 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.

Pulsed light FT handpiece:
Permanent hair reduction, photocoagulation of 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:
<table>
<tr><th>Pulsed light wavelength range</th><th>Hair reduction</th><th>Vascular lesions</th><th>Blood vessels</th><th>Pigmented lesions</th></tr>
<tr><td>500 – 1200 nm</td><td>–</td><td>Skin Types I, II</td><td>Skin Types I, II</td><td>–</td></tr>
<tr><td>520 – 1200 nm</td><td>–</td><td>Skin Type III</td><td>Skin Type III</td><td>Skin Types I, II</td></tr>
<tr><td>550 – 1200 nm</td><td>Skin Types I, II</td><td>–</td><td>–</td><td>Skin Type III</td></tr>
<tr><td>600 – 1200 nm</td><td>Skin Type III</td><td>–</td><td>–</td><td>–</td></tr>
<tr><td>650 – 1200 nm</td><td>Skin Type IV</td><td>–</td><td>–</td><td>Skin Type IV</td></tr>
</table></td><td></td></tr>
<tr><td colspan="4">755 nm LASER (not available for SYMPHONY)</td></tr>
<tr><td>Laser Type</td><td>Alexandrite</td><td>Alexandrite</td><td>Identical</td></tr>
<tr><td>Wavelength (nm)</td><td>755nm</td><td>755 nm</td><td>Identical</td></tr>
</table>

Device Trade Name	Subject Device **AGAIN PRO family**	Predicate Device **K150516** **SYNCHRO REPLA:Y**	Comment
Max Fluence (J/cm^2) *	600 (J/cm^2)	600 (J/cm^2)	Identical
Handpiece Spot Sizes (diameter millimeter)	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	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	Almost identical, different maximum spot size but same fluence range. Change do not affect safety and effectiveness of the device
Pulse Duration (milliseconds)	0.2 to 300 ms	0.25 to 300 ms	Almost identical, minimum pulse duration is slightly different. Change do not affect safety and effectiveness of the device
Pulse Repetition Rate (Hz)	Up to 12 Hz	Up to 10 Hz	Similar, maximum frequency is slightly different.

Device Trade Name	Subject Device **AGAIN PRO family**	Predicate Device **K150516** **SYNCHRO REPLA:Y**	Comment
			Change do not affect safety and effectiveness of the device
Skin Cooling System	Yes, optional	Yes, optional	Identical
1064 nm LASER			
Laser Type	Nd:YAG	Nd:YAG	Identical
Wavelength (nm)	1064 nm	1064 nm	Identical
Max Fluence (J/cm^2)*	600 (J/cm^2)	600 (J/cm^2)	Identical
Handpiece Spot Sizes (Diameter millimetre)	2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm 22 mm	2.5 mm 5 mm 7 mm 10 mm 12 mm 14 mm 15 mm 16 mm 18 mm 20 mm 22 mm	Almost identical, different maximum spot size but same fluence range. Change do not affect safety and effectiveness of the device

Device Trade Name	Subject Device **AGAIN PRO family**	Predicate Device **K150516** **SYNCHRO REPLA:Y**	Comment
	24 mm 30 mm	24 mm	
Pulse Duration (milliseconds)	0.2 to 300 ms	0.25 to 300 ms	Almost identical, minimum pulse duration is slightly different. Change do not affect safety and effectiveness of the device.
Pulse Repetition Rate (Hz)	Up to 12 Hz	Up to 10 Hz	Similar, maximum frequency is slightly different. Change do not affect safety and effectiveness of the device.
Skin Cooling System	Yes, optional	Yes, optional	Identical

*Maximum fluence is not available for all spot sizes.

Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the DEKA AGAIN PRO 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 2-22: 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.

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, "Content of Premarket Submission for Device Software Functions".

Conclusion:

Based on the comparison of indications for use and the technological characteristics, we can conclude that DEKA AGAIN PRO device is as safe, as effective, and performs as well as the legally marketed predicate device (K150516).

Additional Information:

None.