May 16, 2024

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

Re: K240752
Trade/Device Name: Deka Toro
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: March 19, 2024
Received: March 19, 2024

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
Digitally signed by Tanisha L. Hithe -S
Date: 2024.05.16 12:49:41 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & Infection Control Devices,
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240752

Device Name
Deka Toro

Indications for Use *(Describe)*

785 nm laser source
Intended for removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.

1064 & 532 nm laser sources in Q-Switched, nanosecond mode
Intended for treatment of benign vascular lesions, benign pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to:

532 nm (Q-Switched, nanosecond mode), including microbeam handpieces:
- Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos
- Treatment of benign vascular lesions including, but not limited to:
  - port wine birthmarks
  - telangiectasias
  - spider angioma
  - Cherry angioma
  - Spider nevi
- Treatment of benign pigmented lesions including, but not limited to:
  - cafe-au-Iait birthmarks
  - Ephalides, solar lentigines
  - senile lentigines
  - Becker's nevi
  - freckles
  - common nevi
  - nevus spilus
  - Ota Nevus
- Treatment of seborrheic keratosis
- Treatment of post inflammatory hyperpigmentation
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

1064 nm (Q-Switched, nanosecond mode), including microbeam handpieces:
- Removal of dark ink (black, blue and brown) tattoos
- Removal of benign pigmented lesions including;
  - nevus of Ota
  - Café au lait spot
  - Ephalides, solar lentigo (lentigines)
  - Becker Nevus
  - Nevus spilus
- Treatment of common nevi
- Removal or lightening of unwanted hair
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

1064nm laser source in thermal mode (long-pulse) Intended for:
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary # K240752

DEKA TORO

Submitter:

El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Contact:

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Date Summary Prepared:

March 19, 2024

Device Trade Name:

DEKA TORO

Common Name:

Medical Laser system

Regulation Name:

Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology

Product Code:

GEX

Regulatory Class:

Class II

Regulation Number:

21 CFR 878.4810

Predicate Devices:

QUANTA SYSTYEM CHROME (K202503)

LUTRONIC HOLLYWOOD SPECTRA (K213569)

LASEROPTEK HELIOS 785 Pico (K230373)

Device Description:

TORO device is a DEKA laser system with a wide choice of emission modes, ranging from picosecond to hundreds of microseconds of pulse duration.

The available sources are Nd:YAG lasers at 532 nm and 1064 nm, operating in Q-switched mode, and Ti:Sapphire laser at 785 nm operating in the Picosecond pulse mode.

The Q-switched laser at 1064 nm can also operate in Thermal mode, delivering pulses of hundreds of microseconds.

The laser beam generated by the source is then optically coupled to the articulated arm with a handpiece plugged at its end and delivered to the Patient.

Indications for Use:

785 nm laser source

Intended for removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.

1064 & 532 nm laser sources in Q-Switched, nanosecond mode

Intended for treatment of benign vascular lesions, benign pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to:

532 nm (Q-Switched, nanosecond mode), including microbeam handpieces:

- Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos
- Treatment of benign vascular lesions including, but not limited to:
  - port wine birthmarks
  - telangiectasias
  - spider angioma
  - Cherry angioma
  - Spider nevi
- Treatment of benign pigmented lesions including, but not limited to:
  - cafe-au-lait birthmarks
  - Ephalides, solar lentigines
  - senile lentigines
  - Becker's nevi
  - freckles
  - common nevi
  - nevus spilus
  - Ota Nevus
- Treatment of seborrheic keratosis
- Treatment of post inflammatory hyperpigmentation
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

1064 nm (Q-Switched, nanosecond mode), including microbeam handpieces:

- Removal of dark ink (black, blue and brown) tattoos

- Removal of benign pigmented lesions including;
  - nevus of Ota
  - Café au lait spot
  - Ephalides, solar lentigo (lentigines)
  - Becker Nevus
  - Nevus spilus
- Treatment of common nevi
- Removal or lightening of unwanted hair
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

1064nm laser source in thermal mode (long-pulse)

Intended for:

- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

Comparison with The Predicate Device:

785nm laser source

	Proposed device DEKA Toro	K230373 HELIOS 785 Pico Ti:Sapphire laser (785nm)	COMMENTS
INDICATIONS FOR USE	Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.	Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.	Identical
Product Code	GEX	GEX	Identical
Classification	Class II	Class II	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Identical
Wavelength (nm)	785nm ± 25 nm	785nm ±20%	Identical
Pulse Duration	600 – 900 ps	600 ps	Similar
Pulse Energy (max)	0.2 J	0.2 J	Identical
Fluence (max)	4 J/cm^2	4 J/cm^2	Identical
Max Peak Power	0.33 GW	0.33 GW	Identical
Max Average Power	1 W	2 W	Subset, within the range of the predicate
Spot Size (mm)	2-6 mm	1-8 mm	Subset, within the range of the predicate
Repetition Rate (Hz)	1-5 Hz	1-10 Hz	Subset, within the range of the predicate
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece	Identical

1064nm & 532 nm laser source (Q-Switched, nanosecond mode)

	Proposed device DEKA TORO	K202503 CHROME 1064 & 532 nm (Q-Switched, nanosecond mode)	COMMENTS
INDICATIONS FOR USE	Treatment of benign vascular lesions, benign pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to: 532 nm including microbeam handpieces: Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos Treatment of benign vascular lesions including, but not limited to: - port wine birthmarks - telangiectasias - spider angioma - Cherry angioma - Spider nevi Treatment of benign pigmented lesions including, but not limited to: - cafe-au-Iait birthmarks - Ephalides, solar lentigines - senile lentigines - Becker's nevi - freckles - common nevi - nevus spilus - Ota Nevus Treatment of seborrheic keratosis Treatment of post inflammatory hyperpigmentation Skin resurfacing procedures for the treatment of acne scars and wrinkles. 1064 nm including microbeam handpieces: Removal of dark ink (black, blue and brown) tattoos Removal of benign pigmented lesions including; - nevus of Ota - Café au lait spot - Ephalides, solar lentigo (lentigines) - Becker Nevus - Nevus spilus Treatment of common nevi Removal or lightening of unwanted hair Skin resurfacing procedures for the treatment of acne scars and wrinkles	Treatment of benign vascular lesions, benign pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to treatment of: 532 nm including microbeam handpieces: Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos Treatment of benign vascular lesions including, but not limited to: - port wine birthmarks - telangiectasias - spider angioma - Cherry angioma - Spider nevi Treatment of benign pigmented lesions including, but not limited to: - cafe-au-Iait birthmarks - Ephalides, solar lentigines - senile lentigines - Becker's nevi - freckles - common nevi - nevus spilus - Ota Nevus Treatment of seborrheic keratosis Treatment of post inflammatory hyperpigmentation Skin resurfacing procedures for the treatment of acne scars and wrinkles. 1064 nm including microbeam handpieces: Removal of dark ink (black, blue and brown) tattoos Removal of benign pigmented lesions including; - nevus of Ota - Café au lait spot - Ephalides, solar lentigo (lentigines) - Becker Nevus - Nevus spilus Treatment of common nevi Removal or lightening of unwanted hair Skin resurfacing procedures for the treatment of acne scars and wrinkles	Identical

	Proposed device DEKA TORO	K202503 CHROME 1064 & 532 nm (Q-Switched, nanosecond mode)	COMMENTS
Product Code	GEX	GEX	Identical
Classification	Class II	Class II	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Identical
Wavelength	1064, 532 nm	1064, 532 nm	Identical
Pulse Duration	5 - 12 ns @1064 nm 5 - 12 ns @532 nm	6 - 12 ns @1064 6 - 12 ns @532nm	Similar
Pulse Energy (max)	1.0 J @ 1064 nm 0.5 J @ 532 nm	1.0 J @1064 0.5 J @532	Identical
Fluence	Up to 48 J/cm2 @1064 nm Up to 15 J/cm2 @532nm	Up to 48 J/cm2 @1064 nm Up to 15 J/cm2 @532nm	Identical
Spot Size@1064nm	From 2x2 to 7x7 mm2 squared From 2mm to 9 mm diameter round 8 mm diameter with microbeam 9mm diameter with microbeam	From 2x2 to 7x7 mm2 squared From 2 mm to 8 mm diameter round 8 mm diameter with microbeam 9mm diameter with microbeam	Similar
Spot Size@532nm	From 2x2 to 7x7 mm2 squared From 2mm to 9 mm diameter round 8 mm diameter with microbeam 9mm diameter with microbeam	From 2x2 to 7x7 mm2 squared From 3 mm to 10.5 mm diameter round 8 mm diameter with microbeam 9mm diameter with microbeam	Similar
9mm Microbeam handpiece Fluence per dot	Up to 16.5 J/cm2@1064nm Up to 5.95 J/cm2@532nm	Up to 16.5 J/cm2@1064nm Up to 5.95 J/cm2@532nm	Identical
8mm Microbeam handpiece Fluence per dot	Up to 44.4 J/cm2@1064nm Up to 14.9 J/cm2@532nm	Up to 44.4 J/cm2@1064nm Up to 14.9 J/cm2@532nm	Identical
Repetition Rate (Hz)	Up to 20 Hz @1064nm Up to 20 Hz @532nm	Up to 20 Hz @1064nm Up to 20 Hz @532nm	Identical
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece	Identical

1064 nm laser source, Thermal mode (long-pulse)

	Proposed device DEKA TORO	K213569 HOLLYWOOD SPECTRA 1064nm in Spectra (long-pulse) mode	COMMENTS
INDICATIONS FOR USE	- Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris	- Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris	Identical
Product Code	GEX	GEX	Identical

	Proposed device DEKA TORO	K213569 HOLLYWOOD SPECTRA 1064nm in Spectra (long-pulse) mode	COMMENTS
Classification	Class II	Class II	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Identical
Wavelength (nm)	1064 nm	1064 nm	Identical
Pulse Duration	0.1-0.3 ms	0.3 ms	Similar
Pulse Energy (max)	Up to 1500 mJ	Up to 1500 mJ	Identical
Fluence (J/cm2, max)	Up to 12J/cm2	Up to 12 J/cm2	Identical
Spot Size (mm)	2 mm to 9 mm	1 mm to 8 mm	Similar
Repetition Rate (Hz)	Up to 10Hz	Up to 10 Hz	Identical
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece	Identical

Clinical Performance Data:

None

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the TORO device, according to the following standards:

- ANSI AAMI ES60601-1: 2005 / A1: 2012 / A2: 2020: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2014 / A1: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-22:2019 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: 2005 / A1: 2012 / A2: 2020 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 Submissions for Device Software Functions".

Conclusion:

Based on the comparison of indications for use and the technological characteristics, we can conclude that the DEKA TORO device is as safe, as effective, and performs as well as the legally marketed predicate devices K202503, K230373 and K213569.

Additional Information:

None