January 4, 2023

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

Re: K222221
Trade/Device Name: Deka Helix
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, ONG
Dated: December 2, 2022
Received: December 5, 2022

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); 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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K222221

Device Name
DEKA HELIX

Indications for Use *(Describe)*
The Helix Laser System with its accessories is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery).

CO2 Handpieces
The Helix CO2 handpieces with wavelength of 10600 nm are indicated for use for the particular indications as follows:

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:
* laser skin resurfacing
* laser derm-abrasion
* laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.

Scanning unit
The Helix Scanning unit, with wavelength of 10600 nm is indicated for:
•Laser skin resurfacing (ablation and/or vaporization) of soft tissue
The Helix Scanning unit, with wavelength of 1570 nm, is indicated for:
• Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue
The Helix Scanning unit, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

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

K222221

DEKA HELIX

Submitter:

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Contact:

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Regulatory Affairs Manager & Official Correspondent
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Date Summary Prepared:

July 20, 2022

Device Trade Name:

DEKA HELIX

Common Name:

Powered Laser Surgical Instrument

Classification Name:

Powered laser surgical Instrument

Powered laser surgical instrument with microbeam\fractional output

Product Code:

GEX

ONG

Regulatory Class:

Class II

Classification Number:

21 CFR 878.4810

Predicate Device:

The Alma Hybrid Laser System (K203441)

Device Description:

The Helix system consists of:

• Laser system console (containing the optical bench assembly and laser, the microcontroller control electronics and system software, the high voltage power supply, the laser cooling system, the compressed air-purge system, and the service panel)

• LCD control panel with touch-screen technology: the LCD display provides information on the status and settings of the Helix system with touch-screen technology provided to input commands into the system.

• Two wavelengths – CO2 and 1570 nm

• Articulated arm

• Footswitch

• Delivery devices (CO_2 non-fractional applicators, Scanner CO_2/1570nm fractional applicator)

Electrical specifications are:

100-230V ~ single phase, 50/60 Hz, Absorbed electric power 1500 VA (max)

Indications for Use:

The Helix Laser System with its accessories is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery).

CO_2 handpieces

The Helix CO_2 handpieces, with wavelength of 10600nm, are indicated for use for the particular indications as follows:

Dermatology and Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

laser skin resurfacing
laser derm-abrasion
laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.

Scanning unit

The Helix Scanning unit, with wavelength of 10600 nm is indicated for:
Laser skin resurfacing (ablation and/or vaporization) of soft tissue

The Helix Scanning unit, with wavelength of 1570 nm, is indicated for:
Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue

The Helix Scanning unit, with wavelengths of 10600nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

Comparison with The Predicate Device:

The DEKA HELIX is substantially equivalent to Alma Hybrid Laser System (K203441)

Device Trade Name	Proposed Device **DEKA HELIX**	Predicate Device **The Alma Hybrid Laser System** (K203441)	Comment
Indications for Use	The Helix Laser System with its accessories is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic	The Alma Hybrid Laser System, Delivery Devices, Applicators and Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic	Identical

Device Trade Name	Proposed Device **DEKA HELIX**	Predicate Device **The Alma Hybrid Laser System** (K203441)	Comment
	surgery). CO2 handpieces The Helix CO2 handpieces, with wavelength of 10600nm, are indicated for use for the particular indications as follows: Dermatology and Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: *laser skin resurfacing *laser derm-abrasion *laser burn debridement. Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.	surgery (dermatology and plastic surgery). Hy-Light CO2 The Alma Hybrid CO2 non-fractional applicator, with wavelength of 10600 nm is cleared for use for the particular indications as follows: Dermatology & Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: * laser skin resurfacing * laser derm-abrasion * laser burn debridement. Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation	

Device Trade Name	Proposed Device **DEKA HELIX**	Predicate Device **The Alma Hybrid Laser System** (K203441)	Comment
	Scanning unit The Helix Scanning unit, with wavelength of 10600 nm is indicated for: Laser skin resurfacing (ablation and/or vaporization) of soft tissue The Helix Scanning unit, with wavelength of 1570 nm, is indicated for: Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue The Helix Scanning unit, with wavelengths of 10600nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.	of warts. Pixel The Alma Hybrid Pixel CO2 fractional applicator, with wavelength of 10600 nm is indicated for: The ablation, vaporization and coagulation of soft tissues in dermatology and plastic surgery in the performance of skin resurfacing. ProScan The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for: •Laser skin resurfacing (ablation and/or vaporization) of soft tissue The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for: • Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue The Alma Hybrid ProScan	

Device Trade Name	Proposed Device **DEKA HELIX**	Predicate Device **The Alma Hybrid Laser System** (K203441)	Comment
		CO2 &1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.	
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 ONG	GEX ONG	Identical
System Control	Fully computerized	Fully computerized	Identical
Emission Control	Footswitch Interlock	Footswitch Interlock	Identical
User Interface	Touch-screen display Emergency button Key switch	Touch-screen display Emergency button Key switch	Identical
Cooling System	Closed loop, heat exchanger	Closed loop, heat exchanger	Identical
Emission indicator	Visual Audible	Visual Audible	Identical
Electrical Requirements	100-230 V, 16A 50/60 Hz, single phase	120 VAC, 11 A, 50/60 Hz, single phase 220/230 VAC, 6 A, 50/60 Hz, single phase	Differences do not affect safety and effectiveness.

Device Trade Name	Proposed Device **DEKA HELIX**	Predicate Device **The Alma Hybrid Laser System** (K203441)	Comment
Physical Dimensions and Weight	62 cm x 63 cm x 138/202 cm (erected) ~ 70 Kg	465mm x 533 mm x 1345/1973 mm (erected) ~ 86 Kg	Differences do not affect safety and effectiveness.
Laser Type	RF-excited CO_2 laser, Class 4 Fiber Laser, Class 4	RF-excited CO_2 laser, Class 4 Fiber Laser, Class 4	Identical
CO_2 Handpieces			
Wavelength	10600 nm	10600 nm	Identical
Pilot beam	635nm, 4mW	650 nm, 3mW	Differences do not affect safety and effectiveness.
Spot size (mm)	0.125 – 2.0 mm	0.15 – 3.0 at 50 mm working distance 0.25- 3.1 (Dia.) at 200 mm working distance	Differences do not affect safety and effectiveness
Pulse Duration	10 - 900ms	1-1000 ms	Differences do not affect safety and effectiveness.
Pulse Repetition Frequency	0.2 – 200 Hz	1 – 100 Hz	Differences do not affect safety and effectiveness.
Min output energy	5 mJ	5 mJ	Identical
Output Power	70W	30W, 70W	Differences do not affect safety and effectiveness.
Scanning unit			
Wavelenght	10600 nm and/or 1570 nm	10600 nm and/or 1570 nm	Identical
Pilot beam	635nm, 4mW	650 nm, 3mW	Differences do not affect safety and effectiveness.

Device Trade Name	Proposed Device **DEKA HELIX**	Predicate Device **The Alma Hybrid Laser System** (K203441)	Comment
Scanner	Dual axis scanner	Dual axis scanner	Identical
Tip	Cooled	Cooled	Identical
Spot size @ 10600 nm	0.374mm	0.35 mm@ 100 mm distance	Differences do not affect safety and effectiveness.
Scan size @ 1570 nm	20x20 mm	Up to 30 mm diameter	Differences do not affect safety and effectiveness.
Spot size @ 1570 nm	0.75mm	0.75 mm	Identical
Output energy @ 10600 nm	Max 251mJ	120 (30W model) 240 mJ (70W model)	Differences do not affect safety and effectiveness.
Output energy @ 1570 nm	Max 144mJ	24mJ-144 mJ/pixel	Identical
Beam density @ 10600 nm	61% - 98% untreated tissue between spots	~63% - 97% untreated tissue between spots	Differences do not affect safety and effectiveness.
Beam density @ 1570 nm	Up to 400 pixels/cm2	Up to 390 pixels/cm2	Differences do not affect safety and effectiveness.

Clinical Performance Data:

None

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Helix 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 Helix 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:

On the basis of the comparison with the predicate device and on the non-clinical performance data, we can conclude that DEKA HELIX is as safe, as effective, and performs as well as the legally marketed predicate device (K203441).

Additional Information:

None