October 2, 2018

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

Re: K181867
Trade/Device Name: Deka Smartxide2 Trio
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: July 10, 2018
Received: July 12, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181867

Device Name
DEKA SMARTXIDE2 TRIO

Indications for Use *(Describe)*

The DEKA SmartXide2 Trio CO2 laser is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The DEKA Smartxide2 Trio 940nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open surgery), cutting, vaporization, ablation and coagulation of soft tissues (endoscopic surgery) in medical specialties including: plastic surgery, dermatology, ENT, gynaecology, urology, general surgery, gastroenterology and dental procedures.

The DEKA SmartXide2 Trio 980nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open and endoscopic surgery) in medical specialties including plastic surgery, dermatology, ear, nose and throat and oral surgery (otolaryngology), gynaecology, urology, neurosurgery, general and thoracic surgery, gastroenterology and dental procedures.

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 Smartxide^2 Trio – Special 510(k)

Submitter:

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Contact:

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Date Summary Prepared:

July 10, 2018

Device Trade Name:

Deka Smartxide^2 Trio

Common Name:

Medical Laser system

Classification Name:

Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (GEX)

Classification Number:

21 CFR 878.4810

Equivalent Devices:

DEKA Smartxide^2 (K113504)

Device Description:

The DEKA SmartXide^2 Trio is a medical laser system equipped with a 80W CO_2 laser source and an (optional) 980nm or 940nm 50W diode laser source.
The CO2 laser radiation has a wavelength of 10600nm and is delivered to the treatment area through an articulated arm and a delivery accessory (handpiece/scanner/micromanipulator) connected to its distal end, or through a hollow waveguide.
The articulated arm is an optical assembly that delivers free beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO2 laser beam to travel inside it and along its axis regardless of the arm orientation.
The waveguide consists of a flexible silica capillary whose inside wall has been coated with a durable coating which is highly reflective at the intended wavelength of use.
The waveguides used with DEKA Smartxide^2 Trio are manufactured by Laser Engineering and have been cleared by FDA with K112166.
The diode laser source can be provided in two alternative wavelengths: 940nm and 980nm.

The diode laser radiation is delivered to the treatment area through optical fibers, which are guided to the target tissue with the aid of handpieces. The spot size is effectively the diameter of the fiber being connected to the system.
Emission parameters are selected on the front panel while laser emission is activated by a footswitch. The on-off switch and emergency switch are also located on the front panel of the system.
A warning light is located on the top cover, close to the control panel. Light ON state indicates that the system is enabled and ready.
Overall weight of the device is 100 kg, and the size is 240 cm x 59 cm x 56 cm (H x W x D).
Electrical requirement is 100-120Vac 50/60Hz, 220-230Vac 50Hz, 16A.

The modification to the device is the addition of a hollow waveguide delivery system as an alternative to the articulated arm for the CO_2 laser beam . It allows easier delivery of laser energy to the targeted tissue in some surgical procedures.

The intended use of the modified devices, as described in the labelling, has not changed as a result of the modification.

Intended Use:

CO_2 laser
Incision, excision, ablation, vaporization, and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.
940nm diode laser
Incision, excision, vaporization ablation and coagulation of soft tissues (open surgery), cutting, vaporization, ablation and coagulation of soft tissues (endoscopic surgery) in medical specialties including: plastic surgery, dermatology, ENT, gynaecology, urology, general surgery, gastroenterology and dental procedures.
980nm diode laser
Incision, excision, vaporization ablation and coagulation of soft tissues (open and endoscopic surgery) in medical specialties including plastic surgery, dermatology, ear, nose and throat and oral surgery (otolaryngology), gynaecology, urology, neurosurgery, general and thoracic surgery, gastroenterology and dental procedures.

Substantial equivalence discussion:

The DEKA Smartxide^2 Trio is substantially equivalent to the DEKA Smartxide^2 (K113504).

Feature	**Proposed 510(k) Device** DEKA SmartXide^2 Trio	**Predicate Device** **K113504** DEKA SmartXide^2 Laser System and delivery accessories
CO_2 laser		
Laser type	CO_2 laser - sealed off - RF excited	CO_2 laser - sealed off - RF excited
Wavelength	10.6 μm	10.6 μm
Delivery system	Articulated arm, Waveguide	Articulated arm
Output power	0.1 W to 80 W	0.1 W to 80 W

Feature	**Proposed 510(k) Device** DEKA SmartXide^2 Trio	**Predicate Device** **K113504** DEKA SmartXide^2 Laser System and delivery accessories
Spot size	0.125 mm – 1.5 mm (articulated arm) 0.3 -0.5 mm (waveguide)	0.125 mm – 1.5 mm (articulated arm)
Pulse length	0.04ms to 0.9s	0.04ms to 0.9s
Pulse Rate	5 to 800 Hz	5 to 800 Hz
Aiming beam	635 nm, 5mW max	635 nm, 5mW max
Surgical scanning system	Integrated (HiScan Surg., Endoscan)	Integrated (HiScan Surg., Endoscan)
Diode laser		
Laser type	Semiconductor Diode Laser	Semiconductor Diode Laser
Wavelength (nm)	940, 980 nm	940, 980 nm
Output power	0.5W - 50W	0.5W - 50W
Spot size (mm)	0.2, 0.3, 0.6 mm	0.2, 0.3, 0.6 mm
Laser Operating Modes	CW, pulsed	CW, pulsed
Pulsed mode Ton	5ms to 2s	5ms to 2s
Delivery system	Optical Fiber	Optical Fiber
Aiming beam	630-670nm, 3mW max	630-670nm, 3mW max

The DEKA Smartxide^2 Trio has the same indications for use as the abovementioned predicate device, with same principle of operation and same performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

The following verification and validation activities have been performed on the modified devices:

- Verification of CO_2 laser output using the waveguide. The test methods, acceptance criteria and test results are documented in the Design History File of Smartxide^2 Trio.
- Verification and validation of modified software. The test methods, acceptance criteria and test results are documented in the Design History File of Smartxide^2 Trio.

Conclusion:

We can conclude that the DEKA Smartxide Trio Laser system is substantially equivalent to the predicate device.

Additional Information:

None