February 21, 2018

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

Re: K180193
Trade/Device Name: DEKA SMARTXIDE Family (Smartxide Touch, Smartxide Punto)
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: January 22, 2018
Received: January 24, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K180193

Device Name
DEKA Smartxide family (Smartxide Touch, Smartxide Punto)

Indications for Use *(Describe)*
Incision, excision, ablation, vaporization, and coagulation of body soft tissue including intraoral tissue, in medical specialities including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

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 family of Laser Systems – Special 510(k)

Submitter:

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Contact:

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Date Summary Prepared:

January 22, 2018

Device Trade Name:

Deka Smartxide family (Smartxide Touch, Smartxide Punto)

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 Touch (K172362)

Device Description:

The DEKA Smartxide Family of laser system are medical devices equipped with a 10.600 nm Carbon Dioxide (CO_2) laser source having a maximum power of 30W/50W/60W. The laser energy is delivered to the treatment area via an articulated arm and a delivery accessory connected to its distal end. 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 DEKA Smartxide Family laser is equipped with a Scanning Unit that allows to perform skin resurfacing treatments.

The modifications to the devices are

1) different maximum available output power: 60W, 30W and 50W and
2) different external system and scanner covers for DEKA SmartXide Punto models.

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

Intended Use:

Incision, excision, ablation, vaporization, and coagulation of body soft tissue including intraoral tissue, in medical specialities including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Substantial equivalence discussion:

The DEKA Smartxide family of laser systems is substantially equivalent to the DEKA Smartxide Touch (K172362).

Device Trade Name	**DEKA SMARTXIDE FAMILY OF LASER SYSTEMS**	PREDICATE DEVICE **DEKA SMARTXIDE TOUCH (K172362)**
Laser Type	CO2	CO2
Wavelength	10.6µm	10.6µm
Max Power	30W, 50W (Smartxide Punto) 60W (Smartxide Touch)	40W
Handpieces Spot Sizes	0.2 mm, 0.4 mm	0.2 mm, 0.4 mm
Pulse Duration	0.02 to 70 ms	0.02 to 70 ms
Pulse Rep Rate	5 to 100 Hz	5 to 100 Hz
Scanner Spot size	350µm	350µm
Scanner Focal length (EFL)	100mm	100mm

The DEKA Smartxide family of laser systems has the same indications for use as the abovementioned predicate device, with same principle of operation and essentially the 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 actual maximum laser output for each model (30W, 50W, 60W). The test methods, acceptance criteria and test results are documented in the Design History File of Smartxide Punto and Smartxide Touch.

- Verification of electric safety and EMC compliance for the 60W model as worst case electric configuration. The test methods, acceptance criteria and test results are documented in the Design History File of Smartxide Touch.
- Verification of new covers design specifications for Smartxide Punto.

Conclusion:

We can conclude that the DEKA Smartxide family of laser systems is substantially equivalent to the predicate device.

Additional Information:

None