



November 17, 2017

EL.EN Electronic Engineering Spa
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, 50041 Italy

Re: K172363

Trade/Device Name: Dekka Smartxide Ultraspeed
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: August 22, 2017
Received: August 24, 2017

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

Indications for Use

510(k) Number (if known)

K172363

Device Name

SmartXide UltraSpeed

Indications for Use (Describe)

The SmartXide UltraSpeed laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology, neurosurgery, oculoplastic, orthopedic, pulmonary/thoracic surgery, and urology for surgical and aesthetic applications.

Also, the SmartXide UltraSpeed laser is indicated for periodontal applications such as, but not limited to:

- Removal of diseased or Inflamed soft tissue in the periodontal pocket (sulcular debridement)
- Biopsies
- Frenectomy, Frenum release
- Gingivoplasty
- Papillectomy
- Vestibuloplasty
- Hyperplasia
- Operculectomy
- Drainage (abscess)
- Flap surgery
- Fibroma (nonmalignant tumor, mucosa, tongue)
- Epulis
- Aphthous ulcers
- Removal of soft tissue, cysts, and tumors
- Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary
DEKA SmartXide UltraSpeed

Submitter:

El.En. S.p.A.
 Via Baldanzese, 17
 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:

August 02, 2017

Device Trade Name:

DEKA SmartXide UltraSpeed

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 Smart US 20D/UltraSpeed and Smart Clinic laser (K081181).

Device Description:

DEKA SmartXide UltraSpeed is a 10,600 nm CO₂ laser devices with a maximum power of 40W. The laser source delivers the laser output through interchangeable laser handpieces. Handpiece activation is by footswitch.

Intended Use:

SmartXide UltraSpeed laser is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology, neurosurgery, oculoplastic, orthopedic, pulmonary/thoracic surgery, and urology for surgical and aesthetic applications. Also, the SmartXide UltraSpeed laser is indicated for periodontal applications such as, but not limited to:

- Removal of diseased or Inflamed soft tissue in the periodontal pocket (sulcular debridement)
- Biopsies
- Frenectomy, Frenum release

- Gingivoplasty
- Papillectomy
- Vestibuloplasty
- Hyperplasia
- Operculectomy
- Drainage (abscess)
- Flap surgery
- Fibroma (nonmalignant tumor, mucosa, tongue)
- Epulis
- Aphthous ulcers
- Removal of soft tissue, cysts, and tumors
- Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

Substantial equivalence discussion:

The DEKA SmartXide UltraSpeed is substantially equivalent to the Smart US 20D/UltraSpeed and Smart Clinic laser (K081181).

Device Trade Name	DEKA SmartXide UltraSpeed	Predicate Device K081181 Smart US 20D/UltraSpeed and Smart Clinic lasers
Laser Type	CO ₂	CO ₂
Wavelength (nm)	10600	10600
Power (Watts)	40	Smart US20D/UltraSpeed: 25 Smart Clinic: 50
Spot Sizes (mm)	0.2; 0.4	0.2; 0.4
Exposure	Continuous, single and repeated pulse	Continuous, single and repeated pulse
Pulse width (ms)	0.02-70	0.2-80
Repetition rate (Hz)	5-100	5-100
Aiming beam	Diode laser, 4.0 mW	Diode laser, 1.0 mW

The DEKA SmartXide UltraSpeed 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:

Non clinical Performance Tests according to the following standards have been performed:

- ISO 10993-1 Fourth edition 2009-10-15 biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
- IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- IEC 60601-2-22 Edition 3.1 2012-10, 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 Edition 2.0 2007-03, safety of laser products - part 1: equipment classification, and requirements.

Tests results demonstrated compliance to related standards.

Conclusion:

Base on substantially equivalence discussion and on non Clinical Performance data, we can conclude that the DEKA SmartXide UltraSpeed laser system is substantially equivalent to the predicate device .

Additional Information:

None