DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 5, 2014

Electronic Engineering S.p.A.
Mr. Paolo Peruzzi
Regulatory Affairs Manager
50041 Calenzano (FI)
Italy

Re: K133895
Trade/Device Name: DEKA SmartXide^2 Laser System
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 4, 2014
Received: August 6, 2014

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133895

Device Name
DEKA Smartxide2

Indications for Use *(Describe)*

It 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 thorasic surgery (including open and endoscopic), 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.09.04 14:57:31 -04'00'

510(K) Summary

Submitter:	El.En. S.p.A. Via Baldanzese, 17 50041 Calenzano (FI), Italy
Contact:	Paolo Peruzzi Regulatory Affairs Manager Phone: +39-055-882-6807 Email: p.peruzzi@elen.it
Date Summary Prepared:	December 18, 2013
Device Trade Name:	DEKA SmartXide^2 Laser System
Common Name:	Medical Laser System
Classification Name:	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878.4810
Equivalent Device: Affirm	DEKA SmartXide^2 Laser System (K113504) and Cynosure CO2 Laser (K081424)
	Device Description: DEKA SmartXide^2 is a laser with a wavelength of 10600 nm having a maximal power of 60 Watts. The laser energy is delivered to the treatment area via an articulated arm and a delivery accessory connected to its distal end. Laser activation is by footswitch. Overall weight of the laser is 95 Kg, and the size is 210 x 59 x 56 cm (H x W x D). Electrical requirement is 100-120 Vac 15A, 50-60 Hz, single phase
Intended Use:	The SmartXide^2 laser is indicated for incision, excision, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing. Comparison: The SmartXide^2 laser has the same indications for use, the same principle of operation, the same wavelength and the same pulse energy range as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none

Animal Study Data :	Animal study on sheep's skin was conducted to show the comparative effects of Smartxide laser and Affinity lasers on thermal lesion depth and width as well as ablation depth and width.
Conclusion:	The SmartXide^2 laser is a safe and effective device for the intended