March 20, 2024

El.En. S.p.A.
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, FI 50141
Italy

Re: K240537
Trade/Device Name: Smartxide Pro
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: February 21, 2024
Received: February 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S

Tanisha L. Hithe -S
2024.03.20
13:13:42 -04'00'

Tanisha Hithe
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)*
K240537

Device Name
SMARTXIDE PRO

Indications for Use *(Describe)*
The SMARTXIDE PRO is a medical device indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

SmartXide PRO – Special 510(k)

K240537

Submitter:
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50041 Calenzano (FI), Italy

Contact:
Paolo Peruzzi
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E-mail: p.peruzzi@elen.it

Date Summary Prepared:
March 18, 2024

Device Trade Name:
SMARTXIDE PRO

Manufacturer:
DEKA M.E.L.A. srl
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Common Name:
Laser for Surgery and Dermatology

Regulation Number:
21 CFR 878.4810

Regulation Name:
Laser surgical instrument for use in General and Plastic surgery and in Dermatology

Regulation Class:
Class II

Product Code:
GEX

Predicate Devices:

Smart CO2 (SmartXide, Smart US20D) Lasers with DOT scanner (K072159).

Device Description:

SmartXide PRO is a 10.6µm carbon dioxide laser (CO_2 laser), which is highly absorbed by water. Since tissue is comprised mostly of water, this invisible wavelength is highly effective in the surgical treatment of soft tissues.

Moreover, SmartXide PRO device can be equipped with a scanning unit, called HiScan DOT, which can be connected to the arm to provide high performance in specific fields.

The scanning unit is intended for fractionated skin resurfacing or traditional skin resurfacing.

The modifications to the device consist of a restyling of the device (chassis, cover plastic, dimensions, weight, plastic cover, CPU and GUI), a restyling of HiScan DOT unit.

The intended use of the modified device, as described in the labelling has not changed as a result of the modifications. Labelling itself has been updated also to include general improvements that have been implemented since predicate device clearance and considered as minor changes.

Intended Use:

The SmartXide PRO is a medical device indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties 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 SmartXide PRO device is substantially equivalent to the Smart CO_2 (SmartXide, Smart US20D) lasers with DOT scanner (K072159)

Device Trade Name	Proposed Device **SMARTXIDE PRO**	Predicate Device **Smart CO_2 (SmartXide, Smart US20D) Lasers with DOT scanner (K072159)**	Comment
Indications for Use	The SmartXide PRO is a medical device indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialities including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery.	The Smart CO_2 (SmartXide and Smart US20D) Lasers with DOT scanner are indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery.	Identical

Device Trade Name	Proposed Device **SMARTXIDE PRO**	Predicate Device **Smart CO_2 (SmartXide, Smart US20D) Lasers with DOT scanner (K072159)**	Comment
	The use with the scanning unit is indicated for ablative skin resurfacing.	The use with this scanning unit is indicated for ablative skin resurfacing.	
Laser Type	CO_2	CO_2	Identical
Wavelength (µm)	10.6	10.6	Identical
Power (Watt)	30 W	30 W (SmartXIde) 25 W (Smart US20D)	Identical
Aiming beam	635 nm, 1mW	635-670 nm, 3 mW	Almost identical The difference does not affect safety and effectiveness of the device
Handpiece Spot Sizes (millimiter diameter)	0.2 - 0.4 mm	0.2 - 0.4 mm	Identical
Pulse Width (milliseconds)	1 - 80 ms	0.2 - 80 ms	Subset The difference does not affect safety and effectiveness of the device

Device Trade Name	Proposed Device **SMARTXIDE PRO**	Predicate Device **Smart CO_2 (SmartXide, Smart US20D) Lasers with DOT scanner (K072159)**	Comment
Pulse Rate (Pulse/Second)	5 - 100 Hz	5 - 100 Hz	Identical
Scanning area	Variable based on the pattern selected	Variable based on the pattern selected	Identical

Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the SmartXide DOT device, according to the following standards:

- AAMI/ANSI ES60601-1 – Medical 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.
- IEC 60601-2-22 – Medical electrical equipment – Pat 2-22: Particular requirements for basic and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- IEC 60825-1 – Safety of laser products – Part 4: Equipment classification and requirements.

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, "Content of Premarket Submission for Device Software Functions".

Conclusion:

Based on the comparison of indication for use and the technological characteristics, we can conclude that SmartXide PRO device is safe, as effective, and performs as well as the legally marketed predicate device (K072159).

Additional Information:

None.