March 12, 2024

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

Re: K240497
Trade/Device Name: Smartxide Tetra 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 20, 2024
Received: February 20, 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
2024.03.12
09:07:47 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240497

Device Name

SMARTXIDE TETRA PRO

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.

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

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510(k) Summary
SMARTXIDE TETRA PRO– Special 510(k)

510(k) Submission Number:
K240497

Submitter:
El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Contact:
Paolo Peruzzi
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Date Summary Prepared:
February 20th, 2024

Device Trade Name:
SMARTXIDE TETRA PRO

Common Name:
Medical Laser

Regulation Number:
21 CFR 878.4810

Regulation Name:
Laser Surgical Instrument for use in General and Plastic and in Dermatology

Regulatory Class:
Class II

Product Code:
GEX

Predicate Device:

DEKA Smartxide family (Smartxide Touch, Smartxide Punto) (K180193)

Device Description:
The SMARTXIDE TETRA PRO DEVICE consists of a 10,600nm carbon dioxide laser (CO2) laser with 40W of maximum power. 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 device may be used in combination with scanning units in order to achieve greater predictability and reproducibility. The use with the scanning units is indicated for layer-by-layer char-free ablation, enhancing the safety of the treatment with more uniform, accurate and controllable impact such as ablative skin resurfacing.

The overall weight is approximately 62 kg and the sizes are 42 x 122 x 54cm (W x H x D) with folded articulated arm.
Electrical requirements: 100-230V ~ 50/60Hz, 1200VA (max).

Indications for 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.

Comparison with The Predicate Device:

Device Trade Name	Subject Device **SMARTXIDE TETRA PRO**	Predicate Device K180193 **DEKA Smartxide family (Smartxide Touch, Smartxide Punto)**	Comment
Laser Type	CO_2	CO_2	Identical
Wavelength	10.6μm	10.6μm	Identical
Max Power	40W	30W, 50W (Smartxide Punto) 60W (Smartxide Touch)	In the range of predicate device
Handpieces Spot Sizes	0.2 mm, 0.4 mm	0.2 mm, 0.4 mm	Identical
Pulse Duration	0.02 to 70 ms	0.02 to 70 ms	Identical
Pulse Rep Rate	5 to 100 Hz	5 to 100 Hz	Identical
Scanner Spot size	350μm	350μm	Identical
Scanner Focal length (EFL)	100 mm	100mm	Identical

Clinical Performance Data:

None

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the SMARTXIDE TETRA PRO device, according to the following standards:

- ANSI AAMI ES60601-1Medical 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 - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1: Safety of laser products - Part 1: 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 Submissions for Device Software Functions".

Conclusion:

On the basis of the comparison with the predicate device and on the non-clinical performance data, we can conclude that SMARTXIDE TETRA PRO is deemed to be substantially equivalent to the predicate device for the proposed indications for use.

Additional Information:

None