June 2, 2023

El.en Electroinc Engineering Spa
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, FI 50041
Italy

Re: K231309
Trade/Device Name: Scar 3
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: April 20, 2023
Received: May 5, 2023

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Jianting Wang -S

Jianting Wang
Acting 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)*

Device Name
SCAR 3

Indications for Use *(Describe)*
The SCAR 3 scanner, when used with DEKA CO2 lasers, is indicated for ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery.

The SCAR 3 scanner, when used with DEKA CO2 lasers, is indicated for use in the performance of specific applications in dermatology and plastic surgery as follows:

-The ablation, vaporization, excision, incision, and coagulation of soft tissue in the performance of laser burn debridement

-Laser skin resurfacing (ablation and/or vaporization) for treatment of:
• Wrinkles, rhytids, and furrows (including fine lines and texture irregularities)

-Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
• Acne scars
• Surgical scars

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

SCAR 3 SCANNER FOR DEKA CO_2 LASERS – Special 510(k)

Submitter:

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Contact:

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Date Summary Prepared:

April 20, 2023

Device Trade Name:

SCAR 3

Common Name:

Medical laser scanning unit

Classification Name:

Powered laser surgical instrument (GEX)

Classification Number:

21 CFR 878.4810

Predicate Devices:

SCAR 3 (K211362)

Device Description:

The SCAR 3 scanning unit is an optional scanner that can be connected to DEKA CO2 lasers.

The SCAR 3 is composed of the following components:

- HiScan SCAR 3 head

- HiScan SCAR 3 cable

Laser emission parameters are selected through the GUI of the DEKA laser device to whom the scanner is connected.

Shape and size of the scanning area may also be selected by using the three keys on the scanning head.

The modification to the device consists in the extension of the DEKA CO2 laser whom the SCAR 3 scanner can be connected to. The predicate device SCAR 3 (K211362) has been cleared to be used specifically in conjunction with DEKA Smartxide family; the proposed SCAR 3 scanner can be connected to all DEKA CO2 lasers.

The indications for use of the modified device remain the same. Modification only extends the range of CO2 laser the scanner can be used with.

Indications for Use:

The SCAR 3 scanner, when used with DEKA CO2 lasers, is indicated for ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery.

The SCAR 3 scanner, when used with DEKA CO2 lasers, is indicated for use in the performance of specific applications in dermatology and plastic surgery as follows:

-The ablation, vaporization, excision, incision, and coagulation of soft tissue in the performance of laser burn debridement

-Laser skin resurfacing (ablation and/or vaporization) for treatment of:
• Wrinkles, rhytids, and furrows (including fine lines and texture irregularities)

-Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
• Acne scars
• Surgical scars

Substantial equivalence discussion:

The SCAR 3 scanner when used with DEKA CO2 lasers is substantially equivalent to a legally marketed device, SCAR 3 (K211362).

	Proposed 510(k) Device **SCAR 3**	Predicate Device **SCAR 3** **K211362**	Comparison
Device Trade Name			
Indications for use	The SCAR 3 scanner, when used with DEKA CO2 lasers, is indicated for ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery. The SCAR 3 scanner, when used with DEKA CO2 lasers, is indicated for use in the performance of specific applications in dermatology and plastic surgery as follows: -The ablation, vaporization, excision, incision, and coagulation of soft tissue in the performance of laser burn debridement -Laser skin resurfacing (ablation and/or vaporization) for treatment of: • Wrinkles, rhytids, and furrows (including fine lines and texture irregularities) -Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: • Acne scars	The SCAR 3 scanner, when used with DEKA Smartxide family lasers (K180193), is indicated for ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery. The SCAR 3 scanner, when used with DEKA Smartxide family lasers (K180193), is indicated for use in the performance of specific applications in dermatology and plastic surgery as follows: -The ablation, vaporization, excision, incision, and coagulation of soft tissue in the performance of laser burn debridement -Laser skin resurfacing (ablation and/or vaporization) for treatment of: • Wrinkles, rhytids, and furrows (including fine lines and texture irregularities)	Indications for use are the same. Modification only extend the range of CO2 laser the scanner can be used with

	• Surgical scars	-Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: • Acne scars • Surgical scars	
Product code	GEX	GEX	Identical
Laser Wavelength	10600 nm	10600 nm	Identical
Pulse Energy	2.5-150 mJ	2.5-150 mJ	Identical
Spot Sizes	0.12 mm	0.12 mm	Identical
Pulse Duration	0.1-2.5 ms	0.1-2.5 ms	Identical
Scanning Area	Max 10*10 mm	Max 10*10 mm	Identical
Density (spots per scan %)	1%-25 %	1%-25 %	Identical
Frequency (Hz)	150-450	150-450	Identical

The modification on SCAR 3 does not adversely affect safety and effectiveness of the scanner unit; proposed SCAR 3 and cleared SCAR 3 (K211362) share the same indications for use, principle of operation, specifications and performances.

Performance Data:

The following tests have been performed on the modified device:

- Electrical safety tests according to AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, Cl:2009/(R)2012 and A2:2010/(R)2012 – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

- EMC Tests according to IEC 60601-1-2 Ed. 4.1 :2020 – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests,

- Laser safety tests according to 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

- Laser emission specification validation tests

Conclusion:

Based on the comparison of indications for use and the technological characteristics, we can conclude that SCAR 3 scanner is as safe, as effective, and performs as well as the legally marketed predicate device (K211362).