March 11, 2022

El.En Electronic Engineering Spa
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, Florida 50041

Re: K213658
Trade/Device Name: DEKA Smartperio
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: NVK, GEX
Dated: February 7, 2022
Received: February 10, 2022

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,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K213658

Device Name
DEKA SMARTPERIO

Indications for Use *(Describe)*

The DEKA SmartPerio system is intended to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The DEKA SmartPerio is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system.
The device is intended to be used in dentistry.
The following are the oropharyngeal indications for use:
Abscess Incision and Drainage
Apthous Ulcers Treatment
Biopsies Excision and Incision
Crown lengthening
Hemostatic assistance
Fibroma Removal
Frenectomy
Frenotomy
Gingival Incision and Excision
Gingivectomy
Gingivoplasty
Operculectomy
Oral Papillectomy
Tissue retraction for Impression
Vestibuloplasty.
Selective ablation of enamel (first degree) caries
Exposure of unerupted / partially erupted teeth
Implant recovery
Lesion (tumor) removal
Leukoplakia
Pulpotomy
Pulpotomy as adjunct to root canal therapy
Removal of filling material such as gutta percha or resin as adjunct treatment during root canal retreatment Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility tooth mobility.
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.

K213658

510(K) Summary

DEKA SMARTPERIO – Special 510(k)

Submitter:

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Contact:

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Date Summary Prepared:

January 3, 2022

Device Trade Name:

DEKA SMARTPERIO

Common Name:

Laser, dental, soft tissue

Classification Name:

Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology

Product Code:

NVK, GEX

Regulatory Class:

Class II

Classification Number:

21 CFR 878.4810

Predicate Device:

DEKA SMARTPERIO (K203396)

Device Description:

The DEKA SmartPerio is a Nd:YAG laser device for soft-tissues intraoral treatments. The DEKA SmartPerio system delivers laser through an optical fiber that is guided to the target tissue with the aid of an handpiece and a tip.

The modification to the device consists in the increasing of the average output power from 6W to 10W.

The intended use of the modified device, as described in the labelling, has not changed as a result of the modifications.

Indications for Use:

The DEKA SmartPerio system is intended to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The DEKA SmartPerio is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system.

The device is intended to be used in dentistry.

The following are the oropharyngeal indications for use:

Abscess Incision and Drainage

Apthous Ulcers Treatment

Biopsies Excision and Incision

Crown lengthening

Hemostatic assistance

Fibroma Removal

Frenectomy

Frenotomy

Gingival Incision and Excision

Gingivectomy

Gingivoplasty

Operculectomy

Oral Papillectomy

Tissue retraction for Impression

Vestibuloplasty.

Selective ablation of enamel (first degree) caries

Exposure of unerupted / partially erupted teeth

Implant recovery

Lesion (tumor) removal

Leukoplakia

Pulpotomy

Pulpotomy as adjunct to root canal therapy

Removal of filling material such as gutta percha or resin as adjunct treatment during root canal retreatment Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility tooth mobility.

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 modified DEKA SMARTPERIO is substantially equivalent to the DEKA SMARTPERIO device, cleared by FDA with K203396:

	Proposed 510(k) Device **DEKA SMARTPERIO**	Predicate Device **DEKA SMARTPERIO** **K203396**	Comparison
Device Trade Name			
Indications for use	The DEKA SmartPerio system is intended to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The DEKA SmartPerio is intended for ablating, incising, excising,	The DEKA SmartPerio system is intended to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The DEKA SmartPerio is intended for ablating, incising, excising,	Identical

	vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device is intended to be used in dentistry. The following are the oropharyngeal indications for use: Abscess Incision and Drainage Apthous Ulcers Treatment Biopsies Excision and Incision Crown lengthening Hemostatic assistance Fibroma Removal Frenectomy Frenotomy Gingival Incision and Excision Gingivectomy Gingivoplasty Operculectomy Oral Papillectomy Tissue retraction for Impression Vestibuloplasty. Selective ablation of enamel (first degree) caries Exposure of unerupted / partially erupted teeth Implant recovery Lesion (tumor) removal Leukoplakia Pulpotomy Pulpotomy as adjunct to root canal therapy	vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device is intended to be used in dentistry. The following are the oropharyngeal indications for use: Abscess Incision and Drainage Apthous Ulcers Treatment Biopsies Excision and Incision Crown lengthening Hemostatic assistance Fibroma Removal Frenectomy Frenotomy Gingival Incision and Excision Gingivectomy Gingivoplasty Operculectomy Oral Papillectomy Tissue retraction for Impression Vestibuloplasty. Selective ablation of enamel (first degree) caries Exposure of unerupted / partially erupted teeth Implant recovery Lesion (tumor) removal Leukoplakia Pulpotomy Pulpotomy as adjunct to root canal therapy	

	Removal of filling material such as gutta percha or resin as adjunct treatment during root canal retreatment Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility tooth mobility. Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium.)	Removal of filling material such as gutta percha or resin as adjunct treatment during root canal retreatment Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility tooth mobility. Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium.)	
Product code	NVK, GEX	GEX	Identical
Laser Wavelength	1064 nm	1064 nm	Identical
Energy per Pulse	20-300 mJ	20-300 mJ	Identical
Pulses per Second	10-100 Hz	10-100 Hz	Identical
Pulse duration	100-650 µs	100-650 µs	Identical
Average Power	0.2-10W	0.2-6W	The modification does not adversely affect safety and effectiveness
Aiming Beam wavelength	635 nm	635 nm	Identical
Power of Aiming beam	5 mW	5mW	Identical

Performance data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the modified DEKA SMARTPERIO 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.

Additional non-clinical testing conducted

Additional tests were conducted on the modified DEKA SMARTPERIO, according to the following standards:

- 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.

Conclusion:

Based on the comparison of indications for use and the technological characteristics, we can conclude that the modified DEKA SMARTPERIO is as safe, as effective, and performs as well as the unmodified legally marketed predicate device (K203396).