August 23, 2021

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

Re: K203396
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: August 2, 2021
Received: August 6, 2021

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)*

K203396

Device Name
DEKA SMARTPERIO

Indications for Use *(Describe)*

The DEKA SmartPerio system is intended to perform the following types of intraoral procedures: 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) Summary

## DEKA SMARTPERIO

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

**Contact:**
Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
Phone: +39.055.8826807
E-mail: p.peruzzi@elen.it

**Date Summary Prepared:**

August 2, 2021

**Device Trade Name:**

DEKA SMARTPERIO

**Common Name:**

Nd:YAG Pulsed Laser

**Classification Name:**

Laser surgical instrument for use in general and plastic surgery and in dermatology

**Product Code :**

GEX

**Classification Number:**

21 CFR 878.4810

**Equivalent Device:**

Millennium Dental Technologies, Inc : PerioLase Dental Laser (K030290) (Primary predicate)

**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 DEKA Smartperio device consist s of:

- An AC/DC power supply unit
- CPU controller

- LASER source
- Cooling system
- User interface with LCD touch screen
- Beam delivery system

Laser activation is controlled by footswitch.

Electrical specifications are:

115V ~ single phase, 50/60 Hz, Absorbed electric power1840 VA (max)

**Indications for Use:**

The DEKA SmartPerio system is intended to perform the following types of intraoral procedures: 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.)

**Comparison with the predicate device:**

DEKA SMARTPERIO is substantially equivalent to the Millennium Dental Technologies, Inc PerioLase Dental Laser System (K030290):

| | Proposed 510(k) Device<br>**DEKA SMARTPERIO**<br>**K203396** | Primary Predicate Device<br>**Millennium Dental Technologies, Inc : PerioLase Dental Laser**<br>**K030290** | Comparison |
|---|---|---|---|
| Device Trade Name | | | |
| Indications for use | Intraoral procedures: soft tissue dental, general, oral maxillofacial, and cosmetic surgery.<br><br>Intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system.<br><br>The device is intended to be used in dentistry.<br><br>The following are the oropharyngeal indications for use:<br><br>Abscess Incision and Drainage<br><br>Apthous Ulcers Treatment<br><br>Biopsies Excision and Incision<br><br>Crown lengthening | Intraoral soft tissue dental, general, oral maxillo-facial and cosmetic surgery.<br><br>Intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber optic delivery system.<br><br>The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery.<br><br>The following are the oropharyngeal indications for use:<br><br>Abscess Incision and Drainage<br><br>Apthous Ulcers Treatment<br><br>Biopsies Excision and Incision<br><br>Crown lengthening | Indications for use of proposed device are a sub set of indications for use of the predicate device.<br><br>Proposed device is not intended for: otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery. |

| | | | |
|---|---|---|---|
| | Hemostatic assistance | Hemostatic assistance | |
| | Fibroma Removal | Fibroma Removal | |
| | Frenectomy | Frenectomy | |
| | Frenotomy | Frenotomy | |
| | Gingival Incision and Excision | Gingival Incision and Excision | |
| | Gingivectomy | Gingivectomy | |
| | Gingivoplasty | Gingivoplasty | |
| | Operculectomy | Operculectomy | |
| | Oral Papillectomy | Oral Papillectomy | |
| | Tissue retraction for Impression | Tissue retraction for Impression | |
| | Vestibuloplasty. | Vestibuloplasty. | |
| | Selective ablation of enamel (first degree) caries | Selective ablation of enamel (first degree) caries | |
| | Exposure of unerupted / partially erupted teeth | Exposure of unerupted / partially erupted teeth | |
| | Implant recovery | Implant recovery | |
| | Lesion (tumor) removal | Lesion (tumor) removal | |
| | Leukoplakia | Leukoplakia | |
| | Pulpotomy | Pulpotomy | |
| | Pulpotomy as adjunct to root canal therapy | 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. | 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.) | Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium.) | |

| | | | |
|---|---|---|---|
| Product code | 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 | 0.2-6W | 0.2-6W | Identical |
| Aiming Beam wavelength | 635 nm | 635 nm | Identical |
| Power of Aiming beam | 3 mW | 5mW | Similar, difference in aiming beam power does not affect safety and effectiveness. |
| Delivery system | optical fiber (cleared with K124003, K200234) guided to the target tissue with the aid of handpiece and tip (cleared with K952006) | optical fiber guided to the target tissue with the aid of handpiece and tip | Similar delivery system accessories. Subject device uses already FDA cleared accessories, while for predicate device they are included in the device FDA clearance. This difference does not affect safety and effectiveness. |
| Power Requirements | 115Vac, 50/60 Hz, 16Amps | 110-120 VAC, 50/60 Hz, 8 Amps, Single phase; 200 - 240 VAC, 50 Hz, 4 Amps | Both devices had power requirements consistent with US standards. Difference in power input current does not affect safety and effectiveness. |
| Weight | 38 Kg | 45 lbs. [20.4 Kgs]/38 lbs. [17.2 Kgs] | Difference in weight does not affect safety and effectiveness.. |
| Dimensions | 68x23x65cm | 11" (width) x 19" (depth) x 25" (height) | Difference in dimensions does not affect safety and effectiveness. |
| Biocompatibility | Yes- the only parts that can get in contact with patient have already been cleared by FDA (K124003, K200234, K952006) | YES (predicate device cleared by FDA) | Subject device relies on biocompatibility of accessories already cleared by FDA; no data available from predicate device |

**Clinical Performance Data:**

None

**Non-Clinical Performance Data:**

The DEKA SMARTPERIO has been tested and found in compliance with following standards:

- 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 60601-1-2 Ed. 4 – Medical electrical equipment – part 1-2: general requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbance – Requirements and tests.
- IEC60601-2-22 Ed 3.1 Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- IEC 60825-1 Ed. 3.0 – Safety of laser products – Part 1 : Equipment classification, and requirements.

**Conclusion:**

Based on the comparison of indications for use and the technological characteristics, and on the outcome of non-clinical performance data provided , we can conclude that the DEKA SMARTPERIO is as safe, as effective, and performs as well as the legally marketed predicate device.

**Additional Information:**

None.