December 22, 2021

Biolase Inc.
Ed Balcos
Manager, Regulatory Affairs
27042 Towne Centre Drive, Suite 270
Foothill Ranch, California 92610

Re: K213428
Trade/Device Name: EdgePro
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: November 4, 2021
Received: November 22, 2021

Dear Ed Balcos:

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)*
K213428

Device Name
EdgePro

Indications for Use *(Describe)*

Root Canal Hard Tissue Indications (for use on adult and pediatric patients)
- Root canal preparation including enlargement
- Root canal debridement and cleaning

Root Canal Disinfection (for use on adult and pediatric patients)
- Laser root canal disinfection after endodontic treatment

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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BIOLASE

510(k) SUMMARY - K213428

I. SUBMITTER

Biolase, Inc
27042 Towne Centre Drive, Suite 270
Foothill Ranch, CA 92610 USA
Tel: (949) 226-8119
Fax: (949) 273-6677
Contact Person: Ed Balcos
Email: ebalcos@biolase.com
Date Prepared: October 18, 2021

II. DEVICE

Name of Device: **EdgePro**
Common Name: Er,Cr:YSGG Laser
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Device Class: II
Product Code: NVK, GEX

III. PREDICATE DEVICE

Waterlase Express, Biolase, Inc., K161669 (Primary Predicate)

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION EdgePro is an erbium, chromium: yttrium, scandium, gallium garnet (Er,Cr:YSGG)solid-state laser that provides optical energy to the user-controlled distribution of atomized water droplets at 2780 nm. The laser system consists of a top-table console which houses the laser head, power supply, cooling system, micro-processor and a removable tablet PC as a control panel. A flexible fiber cable, connected to the laser console, delivers laser energy to the treatment site through a laser tip attached to a Handpiece. A visible light emitted from the Handpiece head illuminates the area. The laser is activated by means of a wireless footswitch. Various laser tips are available for different clinical applications.
EdgePro utilizes advanced laser and water atomization technologies to cut, shave, contour, roughen, etch and resect oral hard tissues, and direct laser energy, with or without water for cooling and hydration, to perform oral soft tissue removal, incision, excision, ablation and coagulation as well as specific endodontic and periodontal applications.

V. INDICATIONS FOR USE

The EdgePro indications for use are as follows:

Root Canal Hard Tissue Indications (for use on adult and pediatric patients)

- Root canal preparation including enlargement
- Root canal debridement and cleaning

Root Canal Disinfection (for use on adult and pediatric patients)

- Laser root canal disinfection after endodontic treatment

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The EdgePro subject device and the Waterlase Express predicate device are based on the same technological principlesincluding:

- Solid-state Er, Cr;YSGG laser at 2780nm wavelength
- Laser is running at a free-running mode without any additional light modulation features
- Output radiation is pulsed and can be controlled in multiple ways: energy per pulse,pulse duration and pulse repetitionrate
- System contains air/water supply that allows controlled delivery of very precisewater particles to the treatment site
- System is PEMS, programmable embedded medical system

Detailed Description of Changes Made

EdgePro is based on the previously cleared Waterlase Express device (K161669), but limited to previously cleared indications for use;

- **Root Canal Hard Tissue Indications**
  - Root canal preparation including enlargement and
  - Root canal debridement and cleaning
- **Root Canal Disinfection**
  - Laser root canal disinfection after endodontic treatment

EdgePro has changes made to the cosmetic exterior housing and integrated interface/control panel configured to be focused on the limited root canal indications as previously stated.

Summary of technological characteristics between the subject and predicate device is presented in Table 1, below.

BIOLASE

Table 1: Comparison of EdgePro to Waterlase Express

	Subject Device (K213428)	**Predicate Device** (K161669)	**Comparison**
Device Name	EdgePro	Waterlase Express	
Product Code	GEX	GEX	No Change
Application	Dental	Dental	No Change
Laser Medium	Er, Cr: YSGG	Er, Cr: YSGG	No Change
Laser Classification	IV(4)	IV(4)	No Change
Wavelength	2780 nm	2780 nm	No Change
Max Power Output	Up to 2 W	Up to 4 W	Max power of 2W is sufficient for effective root canal indications Therefore, substantially equivalent.
Output Mode	Pulsed	Pulsed	No Change
Max Pulse Energy	100mJ	200 mJ	Lower max pulse energy, is sufficient for effective root canal indications Therefore, substantially equivalent.
Fluence per Spot	10–170 J/cm2	10–170 J/cm2	No Change
Repetition Rate (Frequency)	5-50 Hz	5-50 Hz	No Change

Spot Size	200 – 500 µm	200 – 1,200 µm	Convenience only; therefore, substantially equivalent.

Pulse Duration (Width)	60 µs	60 µs, 700 µs	Eliminated Soft Mode, Hard model is sufficient for effective root canal indications Therefore, substantially equivalent.
Aiming Beam	Diode laser, max 3 mW, 625-670 nm	Diode laser, max 3 mW, 625-670 nm	No Change
Operating Voltage	100 / 230 VAC	100 / 230 VAC	No Change
User Interface / Control Panel	Integrated Display	Tablet PC	Convenience only; therefore, substantially equivalent.
Footswitch	Wireless / Wired	Wireless / Wired	No Change
Labeling	IFU	IFU	Limited to Root Canal Indications; therefore, substantially equivalent.
Materials	Medical grade plastic, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastic, stainless steel, aluminum, brass, and electronic parts and components	No Change

	Subject Device	Predicate Device	Comparison
Indications for Use	**Root Canal Hard Tissue Indications** • Root canal preparation including enlargement • Root canal debridement and cleaning **Root Canal Disinfection** • Laser root canal disinfection after endodontic treatment	**General Hard Tissue Indications (**for use in adult and pediatric patients) • Class I, II, III, IV and V cavity preparation • Caries removal • Hard tissue surface roughening or etching • Enameloplasty, excavation of pits and fissures for placement of sealants **Root Canal Hard Tissue Indications** • Root canal preparation including enlargement • Root canal debridement and cleaning **Root Canal Disinfection** • Laser root canal disinfection after endodontic treatment **Endodontic Surgery (Root Amputation) Indications** • Flap preparation – incision of soft tissue to prepare a flap and expose the bon • Cutting bone to prepare a window access to the apex (apices) of the root(s) • Apicoectomy – amputation of the root end • Root end preparation for retrofill amalgam or composite • Removal of pathological tissues (*i.e.*, cysts, neoplasm or abscess) and hyperplastic tissues (*i.e.*, granulation tissue) from around the apex	Limited to Root Canal Indications; therefore, substantially equivalent.

		NOTE: *Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.* **Bone Surgical Indications** • Cutting, shaving, contouring and resection of oral osseous tissues (bone) • Osteotomy **Soft Tissue Indications including Pulpal Tissues** (for use on adult and pediatric patient) Incision, excision, vaporization, ablation and coagulation of oral soft tissues including: • Excisional and incisional biopsies • Exposure of unerupted teeth • Fibroma removal • Flap preparation – incision of soft tissue to prepare a flap and expose the bone • Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions) • Frenectomy and frenotomy • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis • Implant recovery • Incision and drainage of abscesses • Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery • Leukoplakia	

		• Operculectomy • Oral papillectomies • Pulpotomy • Pulp extirpation • Pulpotomy as an adjunct to root canal therapy • Root canal debridement and cleaning • Reduction of gingival hypertrophy • Soft tissue crown lengthening • Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa • Vestibuloplasty • Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex ***NOTE:*** *Any tissue growth (i.e., cyst, neoplasm or other lesions) must be* *submitted to a qualified laboratory for histopathological evaluation* **Laser Periodontal Procedures** • Full thickness flap • Partial thickness flap • Split thickness flap • Laser soft tissue curettage • Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket • Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium • Removal of granulation tissue from bony defects • Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket	

		to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility) • Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours) • Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.) • Osseous crown lengthening • Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage • Waterlase Er,Cr:YSGG assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium.	
Other changes to labeling or design since the most recently cleared 510(k)	No Change	No Change	No Change

VII. PERFORMANCE DATA

The following performance data were provided in support of substantial equivalence determination:

Biocompatibility Testing

Biocompatibility was not performed for the subject device since the materials as same from the predicate device and theperformance characteristics are equivalent.

Biocompatibility performed for the predicate device evaluation was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within a Risk Management Process, as recognized by the FDA.The battery of testing included cytotoxicity, sensitization, intracutaneous reactivity and systemic toxicity. The results demonstrate biocompatibility of the device.

Electrical Safety and Electromagnetic Compatibility (EMC)

Safety testing of EdgePro was conducted according to recognized standards: IEC 60601-1-2 standard for EMC and IEC60601-1, IEC 60601-2-22, IEC 60825-1 and IEC 80601-2-60 for safety.
The device meets applicable requirements related to the above-referenced standards.

Software Verification and Validation

Software verification and validation testing was performed and documentation was provided as recommended by FDA'sGuidance for Industry and FDA Staff "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices and "Guidance for the Content of Premarket Submission for Management of Cybersecurity in Medical Devices". The results demonstrate that EdgePro performs according to specifications and functions intended.

Bench Testing

Testing was conducted to evaluate performance between the subject device and predicate device. The results demonstrate thatEdgePro performs as well as the predicate device, Waterlase Express.

Clinical Testing

Clinical testing was not performed for the subject device since the indications for use are a subset of the predicate device andthe performance characteristics are equivalent.

VIII. CONCLUSION

EdgePro is substantially equivalent to its legally marketed predicate device, Waterlase Express, in technical characteristics, operating principle and mechanismof action. It has the same indications for use and equivalent performance. Therefore, it can be concluded that EdgePro is as safe and effective as the predicate device.