DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 11, 2017

Biolase, Inc
Alicia Mszyca
Manager, Regulatory Affairs
4 Cromwell
Irvine, California 92618

Re: K163128
Trade/Device Name: Epic 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: December 12, 2016
Received: December 14, 2016

Dear Alicia Mszyca:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163128

Device Name
Epic Pro

Indications for Use *(Describe)*
The Epic Pro with surgical laser operation (Automatic Power Control) used in contact or non-contact mode, is indicated for dental soft tissue indications including: incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extra-oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva); examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted teeth/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, laser assisted flap surgery, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

The Epic Pro with surgical laser operation, used in contact or non-contact mode, is intended for use in general surgery for incision, excision, vaporization, ablation and coagulation of soft tissue.

The Epic Pro with dental laser operation is intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extra-oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva); examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, hemostasis of donor site, treatment of aphthous ulcers, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted teeth/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, laser assisted flap surgery, pulpotomy, pulpotomy as an adjunct to root canal therapy, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), light activation of bleaching materials for teeth whitening.

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

I. SUBMITTER

Biolase, Inc.
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Irvine, CA 92618 USA
Tel: (949) 226-8471
Fax: (949) 273-6688
Contact Person: Alicia Mszyca
Date Prepared: November 4, 2016

II. DEVICE

Name of Device:	**Epic Pro Diode Laser System**
Common Name:	Dental Diode 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:	GEX

III. PREDICATE DEVICE

stLase, K111689

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

Epic Pro diode laser system is a surgical device designed for a wide variety of surgical and oral soft tissue procedures and dental whitening.
Epic Pro utilizes a solid state diode as a semiconductor source for invisible infrared radiation. The energy is delivered to the treatment site via a flexible fiber connected at one end to the laser source and at the other end to the handpiece. Various types of single use disposable tips are designed and optimized for different applications. The device is activated by means of a wireless footswitch.

BIOLASE

V. INDICATIONS FOR USE

The Epic Pro with surgical laser operation (Automatic Power Control) used in contact or non-contact mode, is indicated for dental soft tissue indications including: incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extra-oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva); examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted teeth/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, laser assisted flap surgery, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

The Epic Pro with surgical laser operation, used in contact or non-contact mode, is intended for use in general surgery for incision, excision, vaporization, ablation and coagulation of soft tissue.

The Epic Pro with dental laser operation is intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extra-oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva); examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, hemostasis of donor site, treatment of aphthous ulcers, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted teeth/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, laser assisted flap surgery, pulpotomy, pulpotomy as an adjunct to root canal therapy, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), light activation of bleaching materials for teeth whitening.

VI. SUMMARY OF SIMILARITIES AND DIFFERENCES

Epic Pro is a modified version of its predecessor, stLase (K111689) to include a new delivery system, wireless footswitch, and some software changes which are aimed to improve functionality and user experience. The intended use, indications for use and the fundamental scientific technology of the subject device, Epic Pro, and the predicate device, stLase, are the same.

Similarities:

- The same technical design and operation;
- The same laser source, a semiconductor diode with the wavelength of 980 nm;
- The same max output power of 25W;
- The same aiming beam;
- Both devices are available in continuous wave (CW) and pulsed mode and may be used in contact and non-contact mode;
- Output power in CW mode can be controlled through the thermal feedback signal from end of the fiber (tip);
- Both devices are software-operated and the parameters are controlled by a touch screen control panel;

The key differences between the subject and the predicate device include:

- The predicate device employs a fiber delivery system in the form of strippable fiber consisting of a fiber optic connector, cable, handpiece and disposable adapters to hold fiber in the distal part. The modified device utilizes a detachable fiber cable that is used in conjunction with a multi-tip handpiece and disposable fiber tips;
- The predicate device is activated by means of a wired footswitch, whereas the subject device uses a wireless footswitch;
- Modification of pulse mode, allowing the laser to operate at higher peak powers (up to 150 W) using very short pulses (down to 10 microseconds) with average power below 25 W;
- Output power in pulse mode can also be controlled through the thermal feedback signal from end of the fiber (tip);

Table 1 - Summary of technological characteristics between the subject and predicate device.

Specification	Biolase, Inc **Epic Pro** (subject device)	Biolase, Inc (prior Dental Photonics, Inc.) **stLase/ K111689** (predicate device)
Laser source	Diode	Diode
Wavelength	980 nm	980 nm
Max output power	25 W	25 W
Power range	0.2-25 W	0.5-25 W
Increments	0.2-1 W	0.1-0.5 W
Operating modes	Pulsed or CW	Pulsed or CW
Pulse width (duration)	0.01-100 ms	0.025 - 3 ms
Max pulse peak power	150 W	25 W

Timer duration	50 ms to 99.9 s	50 ms to 99.9 s
Spot size	300 - 400 microns	200 – 400 microns
Fluence per spot	3 – 360 W/mm^2	3 – 800 W/mm^2
Frequency (repetition rate)	Up to 20 kHz	Up to 20 kHz
Aiming beam	650 nm, 5mW	650 nm, 5mW
Cooling	Air cooled	Air cooled
Voltage	120V/60Hz or 240V/50Hz	120V/60Hz or 240V/50Hz
Control panel	Color touch screen	Color touch screen
Laser activation	Wireless footswitch	Wired footswitch
Delivery system	Fiber optic cable, handpiece and disposable fiber tips	Clevable fiber, handpiece holder and disposable tip holder/guide to hold the fiber
Indications for use	Epic Pro with surgical laser operation (Automatic Power Control) used in contact or non-contact mode, is indicated for dental soft tissue indications including: incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues , and	stLase with surgical laser operation (Automatic Power Control) used in contact or non-contact mode is indicated for dental soft tissue indications including: incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues , and

	sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket). Epic Pro with surgical laser operation used in contact or non-contact technique is intended for use in general surgery for incision/excision, vaporization, ablation and coagulation of soft tissue; and Epic Pro with dental laser operation is intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy, and light activation of bleaching	sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket). stLase with surgical laser operation used in contact or non-contact technique is intended for use in general surgery for incision/excision, vaporization, ablation and coagulation of soft tissue; and stLase with dental laser operation is intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy, and light activation of bleaching

	materials for teeth whitening.	materials for teeth whitening.

VII. PERFORMANCE DATA

The following performance data has been generated in support of substantial equivalence determination:

Biocompatibility Testing

The biocompatibility evaluation of the modified device, specifically the patient-contacting elements of the delivery system, 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 and its accessories.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and electromagnetic compatibility testing of Epic Pro was conducted according to the following recognized standards:

- IEC 60601-1-2- Medical electrical equipment – Part 1-2: General requirements for safety – collateral standard: electromagnetic compatibility (EMC)- requirements and test
- IEC 60601-1- Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- 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
- IEC 80601-2-60- Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- IEC 62366-1– Medical devices – Part 1: Application of Usability Engineering to medical devices
- IEC 60601-1-6– Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance -collateral standard: usability

The device passed all the required testing and is in compliance with the above-mentioned standards.

BIOLASE

Software Verification and Validation

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

Bench Testing

In-vitro testing was conducted on soft tissue to evaluate performance between the subject device and its predicate. The results demonstrate that Epic Pro performs as well as the predicate device, stLase.

Clinical Testing

Clinical testing was not performed for the subject device since the indications for use are the same as for the predicate device and the performance characteristics are equivalent.

VIII. CONCLUSION

Epic Pro has the same intended use / indications for use as well as fundamental scientific technology as its legally marketed predicate, stLase (K111689).
Performance data demonstrate that the modifications incorporated to Epic Pro do not raise any new safety or efficacy concerns. The technical design and operation are exactly the same. Therefore, Epic Pro is found to be substantially equivalent to the predicate device.