October 10, 2019

Biolase, Inc.
Alicia Mszyca
Director, Regulatory Affairs
4 Cromwell
Irvine, CA 92618

Re: K190319
Trade/Device Name: Waterlase Laser System Family
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: February 11, 2019
Received: February 13, 2019

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. 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 post-marketing 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,

Purva Pandya
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190319

Device Name
Waterlase Laser System Family

Indications for Use *(Describe)*

Waterlase laser removal of porcelain and ceramic crowns and veneers

General Hard Tissue Indications (for use on 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
• Tooth preparation to obtain access to root canal
• 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 bone
• 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
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.

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.

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BIOLASE

510(k) SUMMARY

I. SUBMITTER

Biolase, Inc.
4 Cromwell
Irvine, CA 92618 USA
Tel: (949) 226-8471
Fax: (949) 273-6688
Contact Person: Alicia Mszyca
Date: August 30, 2019

II. DEVICE

Name of Device:	**Waterlase Laser System Family**
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:	GEX

III. PREDICATE DEVICE

Waterlase Express, Biolase, Inc., K161669
Waterlase MD Turbo Plus, Biolase, Inc., K101658

IV. DEVICE DESCRIPTION

Waterlase Laser System Family utilizes an Er, Cr:YSGG (2780nm) solid-state laser and water atomization technology to safely and effectively cut, shave, contour, roughen, etch and resect oral hard-tissue and direct laser energy to perform oral soft tissue removal, incision, excision, ablation and coagulation. It is also used for specific endodontic and periodontal applications.

A single laser console houses the laser head, power supply, cooling system, micro-processor. The laser is controlled through a display which serves as the User Interface. A flexible fiber optic cable, connected to the laser, 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. A fine water spray is also emitted from the handpiece head to cool and hydrate the issue. A variety of laser tips are available for different clinical applications. The laser is activated by a footswitch.

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V. STATEMENT OF INTENDED USE

Waterlase Laser System Family is intended for use in oral hard and soft tissue dental applications. The Indications for Use are as follows:

Waterlase laser removal of porcelain and ceramic crowns and veneers

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

- Class I, II, III, IV and V cavity preparation
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- 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.

VI. SUMMARY OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The comparison table provided in the Substantial Equivalence section of the submission serves as the basis for the determination of substantial equivalence of the Waterlase Laser System Family to its predicate devices.

The Waterlase Laser System Family has the same intended use, the same technology and design characteristics including energy source, wavelength, laser medium, beam delivery, controls, operating principle and mechanism of action as the predicates.

VII. PERFORMANCE DATA

The results of the following testing have been used to support the submission:

Biocompatibility Testing

The biocompatibility evaluation has been performed in accordance with ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process. The battery of testing included cytotoxicity, sensitization, intracutaneous reactivity and systemic toxicity. The results demonstrate biocompatibility of the patient-contacting components of the device.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing conducted for the Waterlase Laser System Family demonstrate compliance with the current revisions of the recognized standards including IEC 60601-1, IEC 60601-2-22, IEC 60825-1, IEC 80601-2-60 and IEC 60601-1-2.

Software Verification and Validation

Software verification and validation has been conducted, and documentation provided in accordance with the Guidance for the Content of Premarket Submission for Software Contained in Medical Devices. The results demonstrate that the Waterlase Laser System Family performs according to specifications and functions intended.
The software design complies with the IEC 62304 standard - Medical device software-software life cycle processes.

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Bench Testing

Performance bench testing has been completed to determine safety and efficacy when using a laser to remove various ceramic materials from natural teeth. Thermal effects of the laser irradiation on the dentin surfaces and pulpal tissue have been evaluated. The results indicate that the Waterlase Laser System Family is thermally safe for the expanded indications as the irradiation at the maximum power does not increase pulpal temperature to the level that would be considered unsafe.
Effectiveness of the device at the lowest settings has also been demonstrated.

Clinical Testing

No clinical testing has been performed.
Clinical data from published and unpublished scientific literature, further supported by the performance bench testing, demonstrate the ability of the Waterlase Laser System Family to quickly and safely remove porcelain and ceramic restorations without damaging the underlying tooth structure or overheating the surrounding tissue including pulp, and, therefore, can be used as an effective and predictable alternative to the conventional methods.

VIII. CONCLUSION

The Waterlase Laser System Family is substantially equivalent to its legally marketed predicate devices, Waterlase Express (K161669) and Waterlase MD Turbo Plus (K101658), in technical and design characteristics. It has the same functional and performance profile and the same intended use.
The clinical and non-clinical data, included in the submission, support the safety and efficacy of the device for the additional indication for Waterlase laser removal of porcelain and ceramic crowns and veneers.