April 21, 2022

Biolase, Inc.
Ed Balcos
Senior Regulatory Affairs Specialist
27042 Towne Centre Drive, Suite 270
FootHill Ranch, California 92610

Re: K210183
Trade/Device Name: Waterlase iPLus
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, ONG
Dated: January 22, 2021
Received: January 25, 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,

Purva Pandya, D.Eng.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210183

Device Name
Waterlase iPlus Laser System

Indications for Use *(Describe)*

Waterlase iPlus with the fractional handpiece is indicated for use in dermatology for skin resurfacing.

Waterlase iPlus when used with the non-fractional handpieces is indicated for use in the following oral hard and soft tissue dental applications:

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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510(k) SUMMARY

I. SUBMITTER

Biolase,Inc.
27042 Towne Centre Drive
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Foothill Ranch, CA 92610
Tel: (949) 226-8119
Fax: (949) 273-6688
Contact Person: Ed Balcos
Tel: (949) 361-1200
ebalcos@biolase.com
Date: March 21, 2022

II. DEVICE

Name of Device:	**Waterlase iPlus Laser System, Fractional Handpiece**
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, ONG

III. PREDICATE DEVICES

Pearl Fractional Handpiece, Cutera, Inc., K080530
FS-01 Handpiece, Fotona, d.d., K132806

REFERENCE DEVICE

Waterlase iPlus S, Biolase, Inc., K141975

IV. DEVICE DESCRIPTION

Waterlase iPlus utilizes an Er, Cr YSGG (2780nm) solid-state laser and water atomization technology for hard and soft tissue incision, excision, ablation, vaporization and coagulation of soft and hard tissue.

The laser consists of a console the houses the laser head, power supply, cooling system, micro-processor and electronics, a footswitch which activates the laser, and a fiber optic cable for delivery of laser energy through a handpiece to the treatment site. A fine water spray is also emitted from the handpiece to cool and hydrate the issue. The laser is controlled through a touch screen display which serves as the User Interface.

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V. INDICATIONS FOR USE

Waterlase iPlus with the fractional handpiece is indicated for use in dermatology for skin resurfacing.

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grafting, etc.)

- Osseous crown lengthening
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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Subject Device	Predicate (primary)	Predicate (secondary)	Reference Device
Specification	Biolase Fractional Handpiece	Cutera Pearl Fractional Handpiece	Fotona FS01 Fractional Handpiece	Biolase iPlus S
510(k) Number	K210183	K080530	K132806	K141975
Laser medium	Er,Cr YSGG	Er YSGG	Er YAG	Er,Cr YSGG
Wavelength	2780 nm	2790 nm	2940 nm	2780 nm
Operating modes	pulsed	pulsed	pulsed	pulsed
Pulse width, µs	60 µs, 700 µs	≤ 1000 µs	100 us, 300 µs	60 µs, 700 µs
Max Rep Rate	15 Hz	20 Hz	50 Hz	100 Hz
Spot size	250 µm	300 µm	250 µm	200 – 1200µm
Spot spacing	900 µm in x direction, 1 mm in y direction (based on 1.5 cm/sec speed of movement)	0.6 mm (based on 20% density)	1.1 mm	N/A
Max energy per spot	40 mJ	200 mJ	22 mJ	600 mJ
Max fluence per spot	82 J/cm2	280 J/cm2	45 J/cm2	425 J/cm2

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VII. PERFORMANCE DATA

The following non-clinical and clinical performance information was provided in support of substantial equivalence determination:

Biocompatibility Testing

The biocompatibility evaluation for Waterlase iPlus Laser 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 addition of the Fraction Handpiece accessory cytotoxicity testing was completed on the only patient contacting disposable accessory applicator.

Software Verification and Validation

Software verification and validation were conducted, 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 the Waterlase iPlus Laser System performs according to specifications and functions intended. The software design conforms with the IEC 62304 standard - Medical device software- software life cycle processes.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted for the Waterlase iPlus Laser System. The device complies with the current revisions of the recognized standards IEC 60601-1, IEC 60601-2-22, IEC 60825-1, and IEC 80601-2-60 for safety and IEC 60601-1-2 for EMC.

Performance Testing- Bench

In an effort to ensure adding this accessory handpiece to the iPlus Laser System as well as the dermatological indication was as safe and effective as the predicate devices performance bench testing was completed. A verification of the Fractional Handpiece and trunk fiber designs was completed to gather data for peak performance settings. Verification of accessory requirements was also completed, and the accessory passed all requirement criteria.

Performance Testing – Animal

Ex-vivo and in-vivo animal tissue testing was conducted to assess the depth and width of penetration produced with the fractional handpiece. The results support that the device can be used to produce fractional beam micro-ablation depths and widths that are within the range of other fractional laser devices cleared for dermatological skin resurfacing.

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VIII. CONCLUSION

The performance data provided in this submission supports that the device can be used safely and effectively and as intended. The proposed device's fractional handpiece's technology does not raise new types of questions regarding safety and efficacy for it's indications for use when compared to the predicate devices. Based on the above, it can be concluded that the Waterlase iPlus Laser System with Fractional Handpiece is found to be substantially equivalent to the predicate devices.