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

July 28, 2016

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

Re: K161669
Trade/Device Name: Waterlase Express
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: June 15, 2016
Received: June 16, 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,

Christopher J. Ronk -S

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)*
K161669

Device Name
Waterlase Express

Indications for Use *(Describe)*

The Waterlase Express indications for use are as follows:

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)

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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 Prepared: June 14, 2016

II. DEVICE

Name of Device:	**Waterlase Express**
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 MD Turbo Plus, Biolase, Inc., K101658

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

Waterlase Express 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.

Waterlase Express 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.

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V. INDICATIONS FOR USE

The Waterlase Express indications for use are as follows:

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

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- 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.)

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- 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Waterlase Express subject device and the Waterlase MD Turbo Plus predicate device are based on the same technological principles including:

- 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 repetition rate
- System contains air/water supply that allows controlled delivery of very precise water particles to the treatment site
- System is software-operated and the parameters are controlled by a control panel

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

- Lower power output of the subject device compared to the predicate
- Brighter aiming beam for better visibility of the treatment site with max power output of 3mW compared to the predicate device with 1mW aiming beam
- The subject device uses a detachable tablet PC as the control panel / user interface compared to an LCD touchscreen in the predicate device
- The use of a wireless footswitch in the subject device compared to a connected footswitch in the predicate
- The subject device is a smaller table-top unit whereas the predicate device is a floor unit (cabinet)

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

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Table 1: Comparison of Waterlase Express to Waterlase MD Turbo Plus

	Subject Device	**Predicate Device (K101658)**
Device Name	Waterlase Express	Waterlase MD Turbo Plus
Manufacturer	Biolase	Biolase
Laser Medium	Er, Cr: YSGG	Er, Cr: YSGG
Laser Classification	IV(4)	IV(4)
Wavelength	2780 nm	2780 nm
Max Power Output	Up to 4.0 W	Up to10.0 W
Output Mode	Pulsed	Pulsed
Max Pulse Energy	200 mJ	600 mJ
Fluence per Spot	10–170 J/cm2	10–500 J/cm2
Repetition Rate (Frequency)	5-50 Hz	5-100 Hz
Spot Size	200 – 1,200 µm	200 – 1,200 µm
Pulse Duration (Width)	60 µs, 700 µs	60 µs, 700 µs
Aiming Beam	Diode laser, max 3 mW, 625-670 nm, Class 3R	Diode laser, max 1 mW, 635 nm, Class 1
Operating voltage	100 / 230 VAC	100 / 230 VAC
Control Panel / User Interface	Tablet PC	LCD Touchscreen
Footswitch	Wireless	Wired
Indications for Use	**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	**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

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	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:	**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:

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	• 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.*	• 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*

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	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.	**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.

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VII. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the Waterlase Express 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 Waterlase Express was conducted according to recognized standards: IEC 60601-1-2 standard for EMC and IEC 60601-1, 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's Guidance 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 Waterlase Express performs according to specifications and functions intended.

Bench Testing

In-vitro testing was conducted on soft and hard tissue to evaluate performance between the subject device and its predicate. The results demonstrate that Waterlase Express performs as well as the predicate device, Waterlase MD Turbo Plus.

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

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