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

Re: K193486
   Trade/Device Name: Epic 980
   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 13, 2019
   Received: December 17, 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
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/comination-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.


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,

Jessica Mavadia-shukla -S

Jessica Mavadia-Shukla, Ph.D.
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
Indications for Use

Device Name
Epic 980

Dental Soft Tissue Indications

- Incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:
  - Excisional and incisional biopsies
  - Exposure of unerupted teeth
  - Fibroma removal
  - Frenectomy
  - Frenotomy
  - Gingival troughing for crown impressions
  - Gingivectomy
  - Gingivoplasty
  - Gingival incision and excision
  - Hemostasis and coagulation
  - Implant recovery
  - Incision and drainage of abscess
  - Leukoplakia
  - Operculectomy
  - Oral papillectomies
  - Pulpotomy
  - Pulpotomy as an adjunct to root canal therapy
  - Reduction of gingival hypertrophy
  - Soft-tissue crown lengthening
  - Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
  - Vestibuloplasty
  - Tissue retraction for impression
  - Laser soft-tissue curettage
  - Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket
  - Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
  - Reduction of bacterial level (decontamination) and inflammation
  - Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
  - Lesion (tumor) removal
  - Removal of hyperplastic tissues
  - Laser assisted flap surgery
  - Removal of granulation tissue

Whitening
- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth
Pain Therapy

• Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

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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Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
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: December 13, 2019

II. DEVICE

Name of Device: Epic 980
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 DEVICES

Epic 980 (K192430)
QuickLase 980, 810 & Dual (K100474)
SIROLase Advance (K103753)
Elumi 810+980 (K152032)
Curative980 Diode Laser (K082445)

IV. DEVICE DESCRIPTION

The Epic 980 diode laser is a surgical and therapeutic device designated for a wide variety of oral soft-tissue procedures and dental whitening as well as for use in providing a temporary relief of minor pain.

The device uses a solid-state laser diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to a handpiece that emits the energy to the treatment site.

The laser is comprised of a base console, a wireless footswitch which activates the laser and a detachable delivery system consisting of a fiber optic cable, surgical handpiece and single-use disposable tips designed and optimized for different applications.
V. INDICATIONS FOR USE STATEMENT

Dental Soft Tissue Indications
Incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
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- Tissue retraction for impression
- Laser soft-tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Reduction of bacterial level (decontamination) and inflammation
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Lesion (tumor) removal
- Removal of hyperplastic tissues
- Laser assisted flap surgery
- Removal of granulation tissue
Whitening
• Light activation for bleaching materials for teeth whitening
• Laser-assisted whitening/bleaching of teeth

Pain Therapy
• Topical heating for the purpose of elevating tissue temperature for a temporary relief of
  minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor
  sprains and strains, and minor muscular back pain; the temporary

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Epic 980 subject device is the same as Epic 980 (K192430) except for the expanded
indications for use already cleared for devices: Quicklase 810, 980, Dual + (K100474) by
QuickLase Limited, SIROLaser Advance (K103753) by Sirona, Elumi 810 + 980 (K152032) by
Azena Medical, LLC and Curative980 (K082445) by OroScience, Inc.

The Epic 980 shares the same technological characteristic as the predicate devices
including:

• the same laser source: solid state diode producing invisible infrared energy
• the same wavelength: 980nm
• the same intended use: incision, excision, vaporization, ablation and coagulation of
  oral soft tissue
• the same indications for use
• the same patient-contacting components: glass fiber used in contact and non-contact
  mode the same use environment
• the same tissue type and application regimen
• the same principle of operation and emission mode: continuous wave, pulsed or
  both the same control mechanism
• similar design consisting of software-operated portable laser unit, initiated by a
  footswitch similar delivery system comprising of an optical fiber, handpiece and single
  use disposable tips
• the same human factors of user interface

Although some parameters such as maximum power output, power density, pulse rate
differ among the devices, these differences do not result is a significantly different clinical
performance since the settings and used for the expanded indications as well as the
treatment regimen are essentially the same. Therefore, the consolidation of clinical
applications creates no new risks or safety concerns.
Comparison of the technological characteristics, intended use, indications for use of the Epic 980 subject and predicate devices:

<table>
<thead>
<tr>
<th>Subject Device</th>
<th>Predicate Devices</th>
<th>Reference Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specification</td>
<td>Biolase, Inc. Epic 980</td>
<td>Biolase, Inc. Epic 980 (K192430)</td>
</tr>
<tr>
<td>Laser medium</td>
<td>Solid state diode laser</td>
<td>Solid state diode laser</td>
</tr>
<tr>
<td>Wavelength</td>
<td>980 ±10 nm</td>
<td>980 ±10 nm</td>
</tr>
</tbody>
</table>

The devices cleared under K100474 and K152032 operate in 3 different wavelengths: 980nm alone, 810nm alone and dual (810+980 nm). Biolase is claiming equivalence to the 980 nm version only. Therefore, substantially equivalent.

<table>
<thead>
<tr>
<th>Operating modes</th>
<th>Continuous, pulsed</th>
<th>Continuous, pulsed</th>
<th>Continuous, pulsed</th>
<th>Continuous, chopped(pulsed), peak pulse</th>
<th>Pulsed</th>
<th>Continuous, pulsed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Power (CW)</td>
<td>10 W</td>
<td>10 W</td>
<td>10W</td>
<td>7W</td>
<td>2W</td>
<td>10 W</td>
</tr>
</tbody>
</table>

Although Epic 980 is capable of reaching 10W max power, the power settings used for all expanded indications do not exceed 1W, which is sufficient for effective performance and also falls under the maximum power of devices cleared under K103753 and K152032. Therefore, substantially equivalent.

<table>
<thead>
<tr>
<th>Max Peak Power</th>
<th>10 W</th>
<th>10 W</th>
<th>10W @980, or 10W @810, or 20W @ dual</th>
<th>14W</th>
<th>10W @980, or 10W @810, or 20W @ dual</th>
<th>unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repetition rate (Frequency)</td>
<td>Up to 20 kHz</td>
<td>Up to 20 kHz</td>
<td>Up to 20 kHz</td>
<td>Up to 20 kHz</td>
<td>50 Hz</td>
<td>unknown</td>
</tr>
<tr>
<td>Specifications</td>
<td>Epic 980</td>
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<td><strong>Pulse duration</strong></td>
<td>0.01 - 20 ms</td>
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<td><strong>Spot size tips</strong></td>
<td>200 – 400 µm</td>
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<td><strong>Power density</strong></td>
<td>Up to 28294W/cm²</td>
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<td><strong>Aiming beam</strong></td>
<td>diode max 1mW 625 - 670 nm</td>
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<tr>
<td><strong>Control panel</strong></td>
<td>Touch screen</td>
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<td><strong>Activation</strong></td>
<td>Footswitch</td>
<td></td>
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<tr>
<td><strong>Delivery system</strong></td>
<td>Fiber optic cable, handpiece and disposable tips</td>
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<td><strong>Fiber Tips</strong></td>
<td>Quartz single-use tips varying in length and core diameter (200 – 400µm)</td>
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<tr>
<td><strong>Materials</strong></td>
<td>Medical grade plastics, stainless steel, and electronic parts and components</td>
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</tr>
</tbody>
</table>

**Biolase, Inc.**
510(k) - Epic 980
## Intended use and Indications for Use

<table>
<thead>
<tr>
<th>Epic 980 (subject device)</th>
<th>Epic 980 K192430</th>
<th>QuickLase 810,980 &amp; Dual+ K100474</th>
<th>SiroLaser Advance K103753</th>
<th>Elumi 810 + 980 K152032</th>
<th>Curative 980 K082445</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dental soft tissue indications:</strong> incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and interdental gingival and epithelial lining of free gingiva and the following specific indications:</td>
<td><strong>Dental soft tissue indications:</strong> Incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and interdental gingival and epithelial lining of free gingiva and the following specific indications:</td>
<td><strong>Intended for incision, excision, vaporization, hemostasis and treatment of oral soft-tissue. Examples:</strong></td>
<td><strong>Indicated for intra and extraoral surgery including incision, excision, hemostasis, coagulation and vaporization of soft-tissues including marginal and interdental gingival and epithelial lining of free gingiva and is indicated for:</strong></td>
<td><strong>Soft tissue laser intended for the incision, excision, vaporization, hemostasis and treatment of oral soft-tissues. The following are the oropharyngeal indications for use:</strong></td>
<td><strong>Indicated for incision, excision, vaporization, ablation and coagulation of oral soft-tissues (intraoral and extraoral) including marginal and interdental gingival and epithelial lining of free gingiva and the following specific indications:</strong></td>
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<tr>
<td>excisional and incisional biopsies</td>
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<td>exposure of unerupted teeth</td>
<td>exposure of unerupted teeth</td>
<td>exposure of unerupted teeth</td>
<td>exposure of unerupted/partially erupted teeth</td>
<td>exposure of unerupted teeth</td>
<td>exposure of unerupted/partially erupted teeth</td>
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<td>fibroma removal</td>
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<td>gingival troughing for crown impressions</td>
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<td>hemostasis and coagulation</td>
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<td>hemostasis and coagulation</td>
<td>hemostasis of donor site</td>
<td>hemostasis and coagulation</td>
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<td>implant recovery</td>
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<td>incision and drainage of abscess</td>
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<td>pulpotomy as an adjunct to root canal therapy</td>
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<td>soft-tissue crown lengthening</td>
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<td>soft-tissue crown lengthening</td>
<td>soft-tissue crown lengthening</td>
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<td>treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa</td>
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<tr>
<td>vestibuloplasty</td>
<td>vestibuloplasty</td>
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<td>vestibuloplasty</td>
<td>vestibuloplasty</td>
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<tr>
<td>tissue retraction for impression</td>
<td>tissue retraction for impression</td>
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<td>tissue retraction for impression</td>
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<td>laser soft-tissue curettage</td>
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<td>laser soft-tissue curettage</td>
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<td>Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket</td>
<td>Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket</td>
<td>Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket</td>
<td>Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket</td>
<td>Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket</td>
<td>NA</td>
</tr>
<tr>
<td>Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)</td>
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<td>Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)</td>
<td>NA</td>
</tr>
<tr>
<td>Light activation for bleaching materials for teeth whitening</td>
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<td>Light activation for bleaching materials for teeth whitening</td>
<td>Light activation for bleaching materials for teeth whitening</td>
</tr>
<tr>
<td>Laser-assisted whitening/bleaching of teeth</td>
<td>Laser-assisted whitening/bleaching of teeth</td>
<td>Laser-assisted whitening/bleaching of teeth</td>
<td>Laser-assisted whitening/bleaching of teeth</td>
<td>Laser-assisted whitening/bleaching of teeth</td>
<td>Laser-assisted whitening/bleaching of teeth</td>
</tr>
<tr>
<td>Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood</td>
<td>Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood</td>
</tr>
<tr>
<td>Lesion (tumor) removal</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td></td>
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<tr>
<td>------------------------</td>
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</tr>
<tr>
<td>Laser assisted flap surgery</td>
<td>NA</td>
<td>NA</td>
<td>Laser assisted flap surgery</td>
<td>Laser assisted flap surgery</td>
<td></td>
</tr>
<tr>
<td>Removal of granulation tissue</td>
<td>NA</td>
<td>NA</td>
<td>Removal of granulation tissue</td>
<td>Removal of granulation tissue</td>
<td></td>
</tr>
<tr>
<td>Removal of hyperplastic tissues</td>
<td>NA</td>
<td>NA</td>
<td>Removal of hyperplastic tissues</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>
VII. PERFORMANCE DATA

Clinical and Bench Testing
Since the expanded indications for use have been already cleared for equivalent devices, therefore any additional clinical and/or performance testing was not required.

Biocompatibility and Sterilization Testing
No new biocompatibility and sterilization testing were performed. All patient-contacting accessories remain the same as previously cleared under K192430.

Electrical Safety and Electromagnetic Compatibility (EMC)
All relevant electrical safety and EMC testing have been conducted in accordance with current recognized standards. The Epic 980 diode laser complies with the requirements.

IEC 60601-1-2:2014
Medical electrical equipment- Part 1-2- electromagnetic compatibility (EMC)
IEC 60601-1:2012
Medical electrical equipment – Part 1: general requirements for basic safety and essential performance
Medical electrical equipment- Part 2-22: particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1:2014
Safety of laser products- Part 1: equipment classification and requirements
IEC 80601-2-60:2012
Medical electrical equipment – Part 2-60: particular requirements for the basic safety and essential performance of dental equipment

Software Verification and Validation
Software contained in Epic 980 was developed, tested and documented in accordance with IEC 62304:2015 – Medical Device Software - Software Lifecycle and the FDA guidance document “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices”. Verification and validation testing demonstrate performance according to specifications and functions intended.

VIII. CONCLUSION
Comparison of the Epic 980 subject device with the predicate devices demonstrate substantial equivalence in technological and performance characteristics and supports the safety and effectiveness of the Epic 980 for the stated indications for use.