December 4, 2019

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

Re: K192430
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, ILY
Dated: November 8, 2019
Received: November 8, 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 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
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT5: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192430

Device Name
Epic 980

Indications for Use *(Describe)*

1. 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

2. Laser Periodontal Procedures

- 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)

3. Whitening

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

4. 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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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: August 30, 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, ILY

III. PREDICATE DEVICE

Epic 10, K121286
Epic Pro, K163128 (reference device)
SIROLaser Advance +, K170500 (reference device)

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

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 Epic 980 uses an Indium Gallium Arsenide (InGaAs) 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.

A visible light is emitted at the same time to visually identify the treatment location. 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.

BIOLASE

V. INDICATIONS FOR USE

Epic 980 is indicated for

1. Dental soft tissue indications

Incision, excision, vaporization, ablation, and coagulation of oral soft tissue including marginal and inter-dental gingiva 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
- Incisions and draining of abscesses
- 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 impressions

2. Laser Periodontal Procedures

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal packet
- sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

3. Whitening

- Laser activation for bleaching materials for teeth whitening
- Laser assisted whitening /bleaching of teeth

4. Pain Relief

- 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 muscle back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

BIOLASE

VI. SUMMARY OF SIMILARITIES AND DIFFERENCES

The Epic 980 diode laser is identical to the Epic 10 predicate device except for the diode laser module. The 940nm module used in the Epic 10 is replaced with a 980nm module in the Epic 980. The diode is a component from the same diode family with equivalent operating characteristic that does not impact product safety and efficacy.

In addition, two other reference devices were identified to further support the submission. The devices are SIROLaser Advance + (K170500) manufactured by Dentsply Sirona and Epic Pro (K163128) manufactured by Biolase, Inc.
Both generate infrared laser energy via a solid-state diode laser, operate in a similar manner and have been legally marketed for the same intended use and indications for use as the Epic 980.

Detailed comparison of the intended use, indications for use and design of the Epic 980, and the predicate devices is presented in tables below.

	Subject Device	Primary Predicate	Reference Devices	
Specification	Biolase Inc. Epic 980	Biolase Inc. Epic 10 (K121286)	Biolase Inc. Epic Pro (K163128)	Dentsply Sirona SIROLaser Advance + (K170500)
Laser source	Diode (InGaAs)	Diode (InGaAs)	Diode	Diode
Wavelength	980 ± 10 nm	940 ± 10 nm	980 nm ± 20 nm	970 nm (-10 /+ 15nm)
Max output power	10 W	10 W	25W	7W
Operating modes	Continuous, pulse modulation	Continuous, pulse modulation	Pulsed or continuous	Continuous, chopped /peak pulse
Repetition Rate (Frequency)	Up to 20 kHz	Up to 20 kHz	Up to 20 kHz	Up to 20 kHz
Pulse duration	0.01 - 20 ms	0.01 - 20 ms	50ms – 99.9s	0.01 – 0.99 s
Pulse interval (off time between pulses)	0.04 – 20 ms	0.04 – 20 ms	N/A	N/A
Aiming beam	diode, max 1mW, 625 - 670 nm	diode, max 1mW, 625 - 670 nm	diode, max 5mW, 650nm	diode, max 1mW, 660 ± 5nm

Spot size Tips Deep Tissue HP Whitening HP	200 – 400 µm 30mm diameter 35mm x 8mm	200 – 400 µm 30mm diameter 35mm x 8mm	300-400 µm	200,320 µm
Power density	Up to 28294W/cm2	Up to 28294W/cm2	Up to 70736W/cm2	Up to 44563W/cm2
Control panel	Touch screen	Touch screen	Touch screen	Touch screen
Footswitch	Wireless	Wireless	Wireless	Wireless
Delivery system	Fiber optic cable, handpiece and disposable tips	Fiber optic cable, handpiece and disposable tips	Fiber optic cable, handpiece and disposable tips	Fiber optic cable, handpiece and disposable tips
Fiber Tips	Quartz single-use tips varying in length and core diameter (200 – 400µm)	Quartz single-use tips varying in length and core diameter (200 – 400µm)	Quartz single-use tips varying in length and core diameter (300 – 400µm)	Single use tips
Materials	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components

Indications for use

Epic 980 (subject device)	**Epic 10 (primary predicate)**	**Epic Pro (reference device)**	**SIROLaser Advance + (reference device)**
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:	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:	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	Intended for intra and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter - dental gingival and epithelial lining of free gingiva and is indicated for:

excisional and incisional biopsies	excisional and incisional biopsies	biopsy	biopsy
exposure of unerupted teeth	exposure of unerupted teeth	exposure of unerupted teeth /partially erupted teeth;	exposure of unerupted/partially erupted teeth;
fibroma removal	fibroma removal	N/A	fibroma removal
frenectomy	frenectomy	frenectomy	frenectomy
frenotomy	frenotomy	frenotomy	frenotomy
gingival troughing for crown impressions	gingival troughing for crown impressions	gingival troughing	gingival troughing
gingivectomy	gingivectomy	gingivectomy	gingivectomy
gingivoplasty	gingivoplasty	gingivoplasty	gingivoplasty
gingival incision and excision	gingival incision and excision	N/A	gingival incision and excision
hemostasis and coagulation	hemostasis and coagulation	hemostasis of donor site	hemostasis of donor site
implant recovery	implant recovery	implant recovery	implant recovery
incision and drainage of abscess	incision and drainage of abscess	incisions and draining of abscesses;	incisions and draining of abscesses;
leukoplakia	leukoplakia	leukoplakia	leukoplakia
operculectomy	operculectomy	operculectomy	operculectomy
oral papillectomies	oral papillectomies	papillectomy	papillectomy
pulpotomy	pulpotomy	pulpotomy	pulpotomy
pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy,	pulpotomy as an adjunct to root canal therapy
reduction of gingival hypertrophy	reduction of gingival hypertrophy	N/A	reduction of gingival hypertrophy
soft-tissue crown lengthening	soft-tissue crown lengthening	crown lengthening	crown lengthening
treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	treatment of aphthous ulcers	treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
vestibuloplasty	vestibuloplasty	vestibuloplasty	vestibuloplasty

tissue retraction for impression	tissue retraction for impression	tissue retraction for impressions	tissue retraction for impression
Laser Periodontal Procedures			
laser soft-tissue curettage	laser soft-tissue curettage	N/A	laser soft-tissue curettage
laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket	laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket	N/A	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)	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)	sulcular debridement (removal of diseased or inflamed soft tissue in 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)
Whitening			
light activation for bleaching materials for teeth whitening	light activation for bleaching materials for teeth whitening	light activation of bleaching materials for teeth whitening.	light activation for bleaching materials for teeth whitening
laser-assisted whitening/bleaching of teeth	laser-assisted whitening/bleaching of teeth	N/A	laser-assisted whitening/bleaching of teeth
Pain Therapy (Low Level laser 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	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	N/A	Intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for

local blood circulation; the temporary relaxation of muscle.	local blood circulation; the temporary relaxation of muscle.		the temporary increase in local blood circulation and/or temporary relaxation of muscle.

VII. PERFORMANCE DATA

The following information was provided to support the submission:

Biocompatibility Testing

The biocompatibility evaluation of the modified device was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process
The results demonstrate biocompatibility of the device and its accessories.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and electromagnetic compatibility testing conducted according to the current revisions of recognized standards demonstrate compliance with the standards:

- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for safety –electromagnetic compatibility (EMC)- requirements and tests.
- 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 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance -collateral standard: usability

Software Verification and Validation

Software contained in the Epic 980 was developed in accordance with IEC 62304. Software verification and validation testing were performed, and documentation provided in accordance with the FDA guidance document “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices”.

Bench Testing

Ex-vivo testing was conducted on soft tissue to compare performance of the subject device to its predicate. The results demonstrate equivalency.

Clinical Testing

Clinical testing was not performed since there was no change to the intended use and indications for use and the performance characteristics between the subject device and its predicate is equivalent.

VIII. CONCLUSION

Comparison of the Epic 980 subject device with Epic 10 primary predicate (K121286), and two additional reference devices Epic Pro (K163128) and SIROLaser Advance+ (K170500), demonstrates the safety and effectiveness of the Epic 980 and supports substantial equivalence to the identified legally-marketed devices.