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

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,

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

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)*
K193486

Device Name
Epic 980

Indications for Use *(Describe)*

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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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.

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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
- 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
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- Tissue retraction for impression
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- 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.

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Comparison of the technological characteristics, intended use, indications for use of the Epic 980 subject and predicate devices:

	Subject Device	Predicate Devices				Reference Device
Specification	Biolase Inc. Epic 980	Biolase, Inc. **Epic 980 (K192430)**	QuickLase Limited **QuickLase 980, 810 and Dual+ (K100474)**	Sirona **SIROLaser Advance (K103753)**	Azena Medical, LLC **Elumi 810 + 980 (K152032)**	OroScience, Inc. **Curative980 Diode Laser (K082445)**
Laser medium	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser
Wavelength	980 ±10 nm	980 ±10 nm	980 ± 10 nm, or 810 ± 10nm, or dual (810+980)	970 ± 15nm	980 ±10 nm, or 810 ± 10nm, or dual (810+980)	980 ± 10 nm
	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.					
Operating modes	Continuous, pulsed	Continuous, pulsed	Continuous, pulsed	Continuous, chopped(pulsed), peak pulse	Pulsed	Continuous, pulsed
Max Power (CW)	10 W	10 W	10W	7W	2W	10 W
	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.					
Max Peak Power	10 W	10 W	10W @980, or 10W @810, or 20W @ dual	14W	10W @980, or 10W @810, or 20W @ dual	unknown
Repetition rate (Frequency)	Up to 20 kHz	Up to 20 kHz	Up to 20 kHz	Up to 20 kHz	50 Hz	unknown

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Pulse duration	0.01 - 20 ms	0.01 - 20 ms	50, 30, 10ms	0.01 – 0.99 s	variable	unknown
Spot size tips	200 – 400 µm	200 – 400 µm	400 µm	200 - 320 µm	400 µm	unknown
Power density	Up to 28294W/cm²	Up to 28294W/cm²	Up to 15915W/cm²	Up to 44563W/cm²	Up to 3138W/cm²	unknown
Aiming beam	diode max 1mW 625 - 670 nm	diode max 1mW 625 - 670 nm	diode max 5mW 640 - 650nm	diode, max 1mW 635 - 650nm	diode max 5mW 640 - 660nm	diode 650nm
Control panel	Touch screen	Touch screen	Touch screen	Touch screen	Touch screen	Touch screen
Activation	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch
Delivery system	Fiber optic cable, handpiece and disposable tips	Fiber optic cable, handpiece and disposable tips	Quarts glass fiber	Fiber optic cable, handpiece and disposable tips	Quartz glass fiber and tips, handpiece and disposable tips	Optical fibers, handpieces 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)	Fiber (400µm)	Single use tips varying in core diameter (200 - 320 µm)	Quarts tips (400µm)	Single use tips
Materials	Medical grade plastics, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components

Epic 980 (subject device)	**Epic 980 K192430**	**QuickLase 810,980 & Dual+ K100474**	**SiroLaser Advance K103753**	**Elumi 810 + 980 K152032**	**Curative 980 K082445**
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:	Intended for incision, excision, vaporization, hemostasis and treatment of oral soft-tissue. Examples:	Indicated for intra and extraoral surgery including incision, excision, hemostasis, coagulation and vaporization of soft-tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and is indicated for:	Soft tissue laser intended for the incision, excision, vaporization, hemostasis and treatment of oral soft-tissues. the following are the oropharyngeal indications for use:	Indicated for incision, excision, vaporization, ablation and coagulation of oral soft-tissues (intraoral and extraoral) including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:
excisional and incisional biopsies	excisional and incisional biopsies	excisional and incisional biopsies	biopsies	excisional and incisional biopsies	excisional and incisional biopsies
exposure of unerupted teeth	exposure of unerupted teeth	exposure of unerupted teeth	exposure of unerupted/ partially erupted teeth	exposure of unerupted teeth	exposure of unerupted/ partially erupted teeth
fibroma removal	fibroma removal	fibroma removal	fibroma removal	fibroma removal	fibroma removal
frenectomy	frenectomy	frenectomy	frenectomy	frenectomy	frenectomy
frenotomy	frenotomy	frenotomy	frenotomy	frenotomy	frenotomy
gingival troughing for crown impressions	gingival troughing for crown impressions	gingival troughing for crown impressions	gingival troughing	gingival troughing for crown impressions	gingival troughing for crown impressions
gingivectomy	gingivectomy	gingivectomy	gingivectomy	gingivectomy	gingivectomy
gingivoplasty	gingivoplasty	gingivoplasty	gingivoplasty	gingivoplasty	gingivoplasty

gingival incision and excision	gingival incision and excision	gingival incision and excision	gingival incision and excision	gingival incision and excision	gingival incision and excision
hemostasis and coagulation	hemostasis and coagulation	hemostasis and coagulation	hemostasis of donor site	hemostasis and coagulation	hemostasis and coagulation
implant recovery	implant recovery	implant recovery	implant recovery	implant recovery	implant recovery
incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess
leukoplakia	leukoplakia	leukoplakia	leukoplakia	leukoplakia	leukoplakia
operculectomy	operculectomy	operculectomy	operculectomy	operculectomy	operculectomy
oral papillectomies	oral papillectomies	oral papillectomies	papillectomy	oral papillectomies	oral papillectomies
pulpotomy	pulpotomy	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	pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy
reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy
soft-tissue crown lengthening	soft-tissue crown lengthening	soft-tissue crown lengthening	crown lengthening	soft-tissue crown lengthening	soft-tissue 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 canker sores, herpetic and aphthous ulcers of the oral mucosa	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 canker sores, herpetic and aphthous ulcers of the oral mucosa
vestibuloplasty	vestibuloplasty	vestibuloplasty	vestibuloplasty	vestibuloplasty	vestibuloplasty
tissue retraction for impression	tissue retraction for impression	tissue retraction	tissue retraction for impression	tissue retraction	tissue retraction for impression
laser soft-tissue curettage	laser soft-tissue curettage	laser soft-tissue curettage	laser soft-tissue curettage	laser soft-tissue curettage	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	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	laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket	NA
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, 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, 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)
light activation for bleaching materials for teeth whitening	light activation for bleaching materials for teeth whitening	light activation for bleaching materials for teeth whitening	NA	light activation for 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	laser-assisted whitening/bleaching of teeth	NA	laser-assisted whitening/bleaching of teeth	laser-assisted whitening/bleaching of teeth
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	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	NA	NA	NA	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.	circulation; the temporary relaxation of muscle.				circulation; the temporary relaxation of muscle.
Reduction of bacterial level(decontamination) and inflammation	NA	Reduction of bacterial level (decontamination) and inflammation	NA	Reduction of bacterial level (decontamination) and inflammation	Reduction of bacterial level (decontamination) and inflammation
Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium	NA	Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium	NA	Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium	NA
Lesion (tumor) removal	NA	Lesion (tumor) removal	NA	Lesion (tumor) removal	NA
Laser assisted flap surgery	NA	NA	Laser assisted flap surgery	NA	Laser assisted flap surgery
Removal of granulation tissue	NA	NA	Removal of granulation tissue	NA	Removal of granulation tissue
Removal of hyperplastic tissues	NA	NA	Removal of hyperplastic tissues	NA	NA

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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

IEC 60601-2-22:2007+ A1:2012
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.