March 10, 2022

Guilin Woodpecker Medical Instrument Co., Ltd.
% Fu Ailing
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian
Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518055
China

Re: K210367
Trade/Device Name: D-Laser Blue, D-Laser 16
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: NVK, ILY, GEX
Dated: January 11, 2022
Received: January 11, 2022

Dear Fu Ailing:

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,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K210367

Device Name

D-Laser Blue, D-Laser 16

Indications for Use *(Describe)*

D-Laser Blue and D-Laser 16 are intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty ; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; 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 inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening: D-Laser Blue and D-Laser 16 are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: D-Laser Blue and D-Laser 16 are 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 the temporary increase in local blood circulation and/or temporary relaxation of muscles.

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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004_510(k) Summary

004_510(k) Summary

K210367

This summary of 510(K) safety and effectiveness is submitted according to requirements of SMDA and 21 CFR §807.92.

5.1 Administrative Information

Date of Summary prepared	November 10, 2020
Manufacturer information	Submitter's Name: Guilin Woodpecker Medical Instrument Co., Ltd. Address: Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004, China Contact person: Yang Yunfeng TEL: +86-773-2350532 FAX: +86-773-5822450 Mail: ipr@glwoodpecker.com
Submission Correspondent	Company Name: Shenzhen Joyantech Consulting Co., Ltd. Address: Room 1713A, 17 Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong, 518055, China Contact person: Ms. Fu Ailing E-Mail: aileen@cefda.com
Establishment registration number	3005581016

5.2 Device Information

Type of 510(k) submission:	Traditional
Common Name:	Dental Diode Lasers
Trade Name:	D-Laser Blue, D-Laser 16
Model:	D-Laser Blue, D-Laser 16
Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Review Panel:	General & Plastic Surgery
Primary Product Code:	NVK

Secondary Product Codes	GEX, ILY
Device Class:	II
Regulation Number:	21 CFR 878.4810

5.3 Predicate Devices and Reference Devices

Predicate Devices

Sponsor:	Dentsply Sirona	Dentsply Sirona
Device:	SIROLaser Blue	SIROLaser Advance+
510(K) Number:	K180044	K170500

Reference Devices

Sponsor:	Sirona Dental Systems GmbH	Biolase, Inc	Iridex Corporation	ILT Systems, Inc.
Device:	SIROLaser Advance	Epic Pro	IQ 630-670	ACL-5500
510(K) Number:	K103753	K163128	K071687	K930210

5.4 Device Description

The dental diode laser systems, D-Laser Blue and D-Laser 16, realize oral soft tissue surgery, periodontal disease, endodontic disease, pain treatment, soft laser therapy and other oral diseases by vaporizing, carbonizing and solidifying the tissue by laser. The device features include: Using a capacitive touch screen which has the clear display and is easy to operate; Built-in large-capacity rechargeable lithium battery with longer time of endurance; The handpiece sleeve and the fiber tip can be autoclaved to prevent from cross infection; Preset more than 20 treatment procedures to reduce the difficulty of use; A secure protection mechanism that automatically shuts down the device after 5 minutes of inactivity.

The D-Laser Blue and the D-Laser 16 respectively consist of a main unit, a laser transmission system and a power adapter. The main unit includes a semiconductor laser, a power supply system and a control device, a safety protection device and a display device.

The D-Laser Blue employs the diodes with wavelengths of 976nm, 650nm and 450nm, and the device emits laser output energy in the infrared, red and blue spectra respectively. The D-Laser 16 employs the diodes with wavelengths of 976nm and 650nm, and the device emits laser output energy in the infrared, red spectra respectively.

5.5 Indications for Use

D-Laser Blue and D-Laser 16 are intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; 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 inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening: D-Laser Blue and D-Laser 16 are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: D-Laser Blue and D-Laser 16 are 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 the temporary increase in local blood circulation and/or temporary relaxation of muscles.

5.6 Indications for Use and Technological Characteristics of the Subject Devices Compared to the Predicate Devices

Table 1 Comparison Between the Indications for Use and Technological Characteristics of D-Laser Blue and those of the Predicate and Reference Devices

Proposed Device	Predicate Device	Reference Devices				Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
Product Code						
NVK, GEX, ILY	GEX, ILY	GEX	GEX	GEX	GEX	/
Regulation Number						
21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	/
Classification						
Class II	Class II	Class II	Class II	Class II	Class II	/
Surgical Indication for Use						
Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft	Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft	Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft	Intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extra-oral soft tissue	Indicated for use in photocoagulation of both anterior and posterior segments including: * Retinal photocoagulation,	Intended for use in dental intraoral soft tissue, general, oral maxilla-facial and cosmetic surgery. It is intended for ablating, incising, excising,	/

Proposed Device	Predicate Device	Reference Devices				Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for:	tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for:	tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for:	(including marginal and interdental gingiva and epithelial lining of free gingiva); examples include:	panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:	aporizing and coagulation of soft /tissues using a fiber optic delivery system. The following are the indications for which the device will be marketed:	
frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy; biopsy; operculectomy;	> proliferative and nonproliferative diabetic retinopathy; > choroidal neovascularization; > branch retinal vein occlusion;	frenectomy; frenotomy;	/
biopsy; operculectomy;	biopsy; operculectomy;	biopsy; operculectomy;			Excision and incision biopsies; operculectomy	/
implant recovery;	implant recovery;	implant recovery;	implant recovery;		N/A	/
gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;		gingivectomy; gingivoplasty;	/

Proposed Device	Predicate Device	Reference Devices				Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
gingival troughing;	gingival troughing;	gingival troughing;	gingival troughing;	> age-related macular degeneration > retinal tears and detachments > retinopathy of prematurity * Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma	N/A	/
crown lengthening;	crown lengthening;	crown lengthening;	crown lengthening;		Soft tissue crown lengthening	/
hemostasis of donor site;	hemostasis of donor site;	hemostasis of donor site;	hemostasis of donor site;		Hemostatic assistance	/
removal of granulation tissue;	removal of granulation tissue;	removal of granulation tissue;	removal of granulation tissue;		N/A	/
laser assisted flap surgery;	laser assisted flap surgery;	laser assisted flap surgery;	laser assisted flap surgery;		N/A	/
debridement of diseased epithelial lining;	debridement of diseased epithelial lining;	debridement of diseased epithelial lining;	debridement of diseased epithelial lining;		N/A	/
incisions and draining of abscesses;	incisions and draining of abscesses;	incisions and draining of abscesses;	incisions and draining of abscesses;		incisions and draining of abscesses;	/
tissue retraction for impressions;	tissue retraction for impressions;	tissue retraction for impressions;	tissue retraction for impressions;		tissue retraction for impressions;	/
papillectomy;	papillectomy;	papillectomy;	papillectomy;		Oral papillectomy	/

Proposed Device	Predicate Device	Reference Devices				Discussion of the differences between proposed device and predicate device
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vestibuloplasty;	vestibuloplasty;	vestibuloplasty;	vestibuloplasty;			
excision of lesions;	excision of lesions;	excision of lesions;	excision of lesions;		N/A	/
exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;		N/A	/
removal of hyperplastic tissues;	removal of hyperplastic tissues;	removal of hyperplastic tissues;	removal of hyperplastic tissues;		N/A	/
treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers;		treatment of aphthous ulcers;	/
leukoplakia;	leukoplakia;	leukoplakia;	leukoplakia;		N/A	/
pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as adjunct to root canal therapy;		N/A	/
fibroma removal; gingival incision and excision;	fibroma removal; gingival incision and excision;	fibroma removal; gingival incision and excision;	N/A		Removal of fibromas; gingival incision and excision;	/

Proposed Device	Predicate Device	Reference Devices				Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
treatment of canker sores; herpetic ulcers of the oral mucosa;	treatment of canker sores; herpetic ulcers of the oral mucosa;	treatment of canker sores; herpetic ulcers of the oral mucosa;	N/A		N/A	
laser soft tissue curettage;	laser soft tissue curettage;	laser soft tissue curettage;	N/A		N/A	/
reduction of gingival hypertrophy.	reduction of gingival hypertrophy.	reduction of gingival hypertrophy.	N/A		N/A	/
Laser Periodontic Indications for Use						
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;	N/A	N/A	N/A	/
sulcular debridement (removal of diseased, infected, inflamed	sulcular debridement (removal of diseased, infected, inflamed	sulcular debridement (removal of diseased, infected, inflamed	sulcular debridement (removal of diseased or inflamed soft tissu	N/A	Sulcular debridement (removal of diseased or inflamed soft	/

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Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability);	and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability);	and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability);	e in the periodontal p ocket)		tissue in the periodontal pocket); Photo initiation of gingival barriers and dams	
Tooth Whitening Indications for Use						
Light activation for bleaching materials for teeth whitening.	Light activation for bleaching materials for teeth whitening.	N/A	Light activation for bleaching materials for teeth whitening.	N/A	Laser-assisted bleaching/whitening of teeth	/
laser-assisted whitening/bleaching of teeth.	laser-assisted whitening/bleaching of teeth.	N/A	N/A	N/A	N/A	/

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Low Level Laser Therapy Indications for Use						
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 the temporary increase in local blood circulation	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 the temporary increase in local blood circulation	N/A	N/A	N/A	N/A	/

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and/or temporary relaxation of muscles.	and/or temporary relaxation of muscles.					
Application						
Dental Laser	Dental Laser	Dental Laser	Dental Laser	IQ Laser	Curing Laser	/
Laser Classification						
976 nm and 450nm Laser: Class IV	970 nm and 445 nm Laser: Class IV	970 nm: Class IV	980 nm: Class IV	630-670 nm	450 nm	According to K180044, K103753 and K163128, the upper limit is 980 nm, the low limit is 970 nm, so 976 nm can be accepted. According to K930210, 450 nm can be accepted.
650 nm Laser: Class II	660 nm Laser: Class II					According to K071687, 650 nm can be accepted.
Laser Type						
Solid state diode	Solid state diode	Solid state diode	Solid state diode	Diode, Diode-	Argon Ion	/

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				pumped, frequency doubled, solid state		
Laser Wavelength						
976 nm (+/-20 nm) (956-996)	970 nm (-10/+15 nm) (960-985)	970 nm (+/-15 nm) (955-985)	980 nm (+/-20 nm) (960-1000)	630-670 nm	450 nm (+/-20 nm) (430-470)	According to K103753, the lowest value 955 nm can be accepted. According to K163128, the highest value 1000 can be accepted. As a result, 956-996 nm can be accepted.
650 nm (+/-20 nm) (630-670)	660 nm (+/-5 nm) (655-665)					According to K071687, 630-670 nm can be accepted.
450 nm (+/-20 nm) (430-470)	445 nm (+/-5 nm) (440-450)					According to K930210, 430-470 nm can be accepted.
Optical Power						
976 nm:	**970 nm**:	**970 nm**:	**980 nm**:	**630-670 nm**:	**450 nm**:	According to K163128, the

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0.2 W - 4 W (Continuous Wave) 7 W (peak power)	0.2 W - 2.0 W (Continuous Wave)	7.0 W max. (Continuous Wave) 14 W (peak optical power)	0.2 W - 25 W	≤ 5W	500 mW	highest value 25W can be accepted, so 0.2 W - 4 W can be accepted.
650 nm: 25 mW-200 mW (Continuous Wave)	**660 nm**: 25 mW, 50 mW, 100 mW (Continuous Wave)					According to K071687, the highest value 5 W can be accepted. According to K180044 and K071687, 25 mW-200 mW can be accepted.
450 nm: 0.2 W - 3.0 W (Continuous Wave) 4 W (peak power)	**445 nm**: 0.2 W - 3.0 W (Continuous Wave)					/
Emission Modalities						
• Continuous Wave • Chopped (1 Hz - 20 kHz)	• Continuous Wave • Chopped (1 Hz - 10 kHz)	• Continuous Wave • Chopped (1 Hz - 10 kHz) • Peak Pulse (up to	• Pulsed or continuous (up to 20 kHz)	• CW (CW-Pulse, MicroPulse, Long Pulse) • Repetition rate≤	N/A	According to K163128, chopped value can be up to 20 kHz, so the emission modalities of the proposed device can be

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		20 kHz)		1kHz		accepted.
Pulse Duration						
Chopped Mode: 5 μsec. To 0.9 sec.	Chopped Mode: 10 μsec. To 0.99 sec.	Chopped Mode: 10 μsec. To 0.99 sec. Peak Pulse: 23 μsec.	50 ms to 99.9 s	10 μsec - 60 min	N/A	According to K163128, the lowest value of the pulse duration can be 50 ms and the highest value 99.9 s, so the range of pulse duration of the proposed device can be accepted.
Alming Beam						
650±20 nm P_{max}＜5 mW	660±5 nm 1 mW (max.)	635 nm- 650 nm 1 mW (max.)	650nm 5mW (max.)	630nm-650nm	N/A	According to K071687, the lowest value 630 can be accepted. According to the performance test report, the highest value 670 nm can be accepted.
Optical Fiber Surgical Tips						

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Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
Fiber Diameter: 200 μm, 300 μm, 400 μm,	Fiber Diameter: 200 μm, 320 μm	Fiber Diameter: 200 μm, 320 μm	• Fiber Diameter: • 300 μm, 400 μm	N/A	Fiber Diameter: 400 μm	According to K180044 and K163128, all fiber diameters of the proposed device can be accepted.
• Single-use tips. • Integral laser fiber. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided non-sterile	• Single-use tips. • Integral laser fiber. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided sterile (sterilized by ethylene oxide).	• Single-use tips. • Laser fiber assembled with tip by user. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided non-sterile	• Quartz single-use tips varying in length and core diameter • Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components • Disposable	• Delivery Devices provided sterile packaged & non-sterile	N/A	/
Laser Handpiece						

Proposed Device	Predicate Device	Reference Devices				Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable stainless steel outer sleeve.	• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable stainless steel outer sleeve.	• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable outer sleeve.	• Handpiece connected by fiber optic cable,		• Disposable, Barrier sleeve	/
Laser Therapy Light Guides						
N/A	• Curved light guides; • 4 mm, 8mm diameter.	N/A	N/A	N/A	N/A	/
Activation Method						
• Handpiece finger	• Handpiece finger	• Handpiece finger	• Wireless	• Footswitch	• FAN forced air	/

Proposed Device	Predicate Device	Reference Devices				Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser Blue (To be decided)	**Dentsply Sirona SIROLaser Blue (K180044)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	**ILT Systems, Inc. ACL-5500 (K930210)**	
switch. • Wireless foot switch.	switch. • Optional wireless foot switch.	switch. • Optional wireless foot switch.	footswitch.			
Laser Control Unit Dimensions						
190 mm x 180 mm x 200 mm	182 mm x 197 mm x 189 mm	182 mm x 197 mm x 189 mm	184 mm x 114 mm x 165 mm	Unknown	Unknown	Different size doesn't affect the substantial equivalence with the predicate.
Laser Control Unit User Interface						
Color touch screen graphical user interface	Color touch screen graphical user interface	Color touch screen graphical user interface	Color touch screen graphical user interface	Manual & Remote Controls	Discreet switches	/

Table 2 Comparison Between the Indications for Use and technological characteristics of D-Laser 16 and those of the Predicate and Reference Devices

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
Product Code					
NVK, GEX, ILY	GEX, ILY	GEX	GEX	GEX	/
Regulation Number					
21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	/
Classification					
Class II	Class II	Class II	Class II	Class II	/
Surgical Indication for Use					
Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and	Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and	Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and	Intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extra-oral soft tissue (including marginal and interdental gingiva and	Indicated for use in photocoagulation of both anterior and posterior segments including: * Retinal photocoagulation, panretinal	/

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
inter-dental and epithelial lining of free gingiva and is indicated for:	inter-dental and epithelial lining of free gingiva and is indicated for:	inter-dental and epithelial lining of free gingiva and is indicated for:	epithelial lining of free gingiva); examples include:	photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:	
frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy; biopsy; operculectomy;	> proliferative and nonproliferative diabetic retinopathy; > choroidal neovascularization; > branch retinal vein occlusion; > age-related macular degeneration > retinal tears and	/
biopsy; operculectomy;	biopsy; operculectomy;	biopsy; operculectomy;			/
implant recovery;	implant recovery;	implant recovery;	implant recovery;		/
gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;		/
gingival troughing;	gingival troughing;	gingival troughing;	gingival troughing;		/
crown lengthening;	crown lengthening;	crown lengthening;	crown lengthening;		/
hemostasis of donor site;	hemostasis of donor site;	hemostasis of donor site;	hemostasis of donor site;		/
removal of granulation tissue;	removal of granulation tissue;	removal of granulation tissue;	removal of granulation tissue;		/

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
laser assisted flap surgery;	laser assisted flap surgery;	laser assisted flap surgery;	laser assisted flap surgery;	detachments > retinopathy of prematurity * Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma	/
debridement of diseased epithelial lining;	debridement of diseased epithelial lining;	debridement of diseased epithelial lining;	debridement of diseased epithelial lining;		/
incisions and draining of abscesses;	incisions and draining of abscesses;	incisions and draining of abscesses;	incisions and draining of abscesses;		/
tissue retraction for impressions;	tissue retraction for impressions;	tissue retraction for impressions;	tissue retraction for impressions;		/
papillectomy; vestibuloplasty;	papillectomy; vestibuloplasty;	papillectomy; vestibuloplasty;	papillectomy; vestibuloplasty;		/
excision of lesions;	excision of lesions;	excision of lesions;	excision of lesions;		/
exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;		/
removal of hyperplastic tissues;	removal of hyperplastic tissues;	removal of hyperplastic tissues;	removal of hyperplastic tissues;		/
treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers;		/

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
leukoplakia;	leukoplakia;	leukoplakia;	leukoplakia;		/
pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as adjunct to root canal therapy;		/
fibroma removal; gingival incision and excision;	fibroma removal; gingival incision and excision;	fibroma removal; gingival incision and excision;	N/A		/
treatment of canker sores; herpetic ulcers of the oral mucosa;	treatment of canker sores; herpetic ulcers of the oral mucosa;	treatment of canker sores; herpetic ulcers of the oral mucosa;	N/A		/
laser soft tissue curettage;	laser soft tissue curettage;	laser soft tissue curettage;	N/A		/
reduction of gingival hypertrophy.	reduction of gingival hypertrophy.	reduction of gingival hypertrophy.	N/A		/
Laser Periodontic Indications for Use					
laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal	laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal	laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal	N/A	N/A	/

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
pocket;	pocket;	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 inability);	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 inability);	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 inability);	sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)	N/A	/
Tooth Whitening Indications for Use					
Light activation for bleaching materials for teeth whitening.	Light activation for bleaching materials for teeth whitening.	N/A	Light activation for bleaching materials for teeth whitening.	N/A	/
Laser-assisted whitening/bleaching of teeth.	laser-assisted whitening/bleaching of teeth.	N/A	N/A	N/A	/

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
Low Level Laser Therapy Indications for Use					
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 the temporary increase in local blood circulation and/or temporary relaxation of muscles.	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 the temporary increase in local blood circulation and/or temporary relaxation of muscles.	N/A	N/A	N/A	/
Application					
Dental Laser	Dental Laser	Dental Laser	Dental Laser	IQ Laser	/

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
Laser Classification					
976 nm Laser: Class IV	970 nm Laser: Class IV	970 nm: Class IV	980 nm: Class IV	630-670 nm	According to K170500 and K163128, 976 nm can be accepted.
650 nm Laser: Class II	660 nm Laser: Class II				According to K071687, 650 nm can be accepted.
Laser Type					
Solid state diode	Solid state diode	Solid state diode	Solid state diode	Diode, Diode-pumped, frequency doubled, solid state	/
Laser Wavelength					
976 nm (+/-20 nm) (956-996)	970 nm (-10/+15 nm) (960-985)	970 nm (+/-15 nm) (955-985)	980 nm (+/-20 nm) (960-1000)	630-670 nm	According to K103753, the lowest value 955 nm can be accepted. According to K163128, the highest value 1000 can be accepted. As a result, 956-996 nm can be

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
					accepted.
650 nm (+/-20 nm) (630-670)	660 nm (+/-5 nm) (655-665)				According to K071687, 630-670 nm can be accepted.
Optical Power					
976 nm: 0.3 W - 7 W (Continuous Wave) 16 W (peak power)	**970 nm**: 0.2 W - 7.0 W (CW) 14 W (peak optical power)	**970 nm**: 7.0 W max. (Continuous Wave) 14 W (peak optical power)	**980 nm**: 0.2 W - 25 W	**630-670 nm**: ≤ 5W	According to K163128, the highest value 25W can be accepted, so 0.2 W - 4 W can be accepted.
650 nm: 25 mW-200 mW (Continuous Wave)	**660 nm**: 25 mW, 50 mW, 100 mW				According to K071687, the highest value 5 W can be accepted. According to K170500 and K071687, 25 mW-200 mW can be accepted.
Emission Modalities					
• Continuous Wave • Chopped (1 Hz - 20 kHz)	• Continuous Wave • Chopped (1 Hz - 10 kHz)	• Continuous Wave • Chopped (1 Hz - 10 kHz)	• Pulsed or continuous (up to 20 kHz)	• CW (CW-Pulse, MicroPulse, Long Pulse) • Repetition rate≤ 1kHz	According to K163128, chopped value can be up to 20 kHz, so the emission modalities

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
	• Peak Pulse (1.5 kHz - 20 kHz)	• Peak Pulse (up to 20 kHz)			of the proposed device can be accepted.
Pulse Duration					
Chopped Mode: 5 µsec. To 0.9 sec.	Chopped Mode: 10 µsec. to 0.99 sec.	Chopped Mode: 10 µsec. To 0.99 sec.	50 ms to 99.9 s	10 µsec - 60 min	According to K163128, the lowest value of the pulse duration can be 50 ms and the highest value 99.9 s, so the range of pulse duration of the proposed device can be accepted.
	Peak Pulse Mode: 23 µsec.	Peak Pulse Mode: 23 µsec.			
Alming Beam					
650±20 nm P_{max}＜5 mW	660±5 nm 1 mW (max.)	635 nm- 650 nm 1 mW (max.)	650nm 5mW (max.)	630nm-650nm	According to K071687, the lowest value 630 can be accepted. According to the performance test report, the highest value 670 nm can be

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
					accepted.
Optical Fiber Surgical Tips					
Fiber Diameter: 200 μm, 300 μm, 400 μm,	Fiber Diameter: 200 μm, 320 μm	Fiber Diameter: 200 μm, 320 μm	• Fiber Diameter: • 300 μm, 400 μm	N/A	According to K180044 and K163128, all fiber diameters of the proposed device can be accepted.
• Single-use tips. • Integral laser fiber. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided non-sterile	• Single-use tips. • Integral laser fiber. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided sterile (sterilized by ethylene oxide).	• Single-use tips. • Laser fiber assembled with tip by user. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided non-sterile	• Quartz single-use tips varying in length and core diameter • Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components • Disposable	• Delivery Devices provided sterile packaged & non-sterile	/

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable stainless steel outer sleeve.	• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable stainless steel outer sleeve.	• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable outer sleeve.	• Handpiece connected by fiber optic cable,		/
Laser Therapy Light Guides					
N/A	• Curved light guides; • 4 mm, 8mm diameter.	N/A	N/A	N/A	/
Activation Method					
• Handpiece finger switch. • Wireless foot switch.	• Handpiece finger switch. • Optional wireless foot switch.	• Handpiece finger switch. • Optional wireless foot switch.	• Wireless footswitch.	• Footswitch	/
Laser Control Unit Dimensions					

Proposed Device	Predicate Device	Reference Devices			Discussion of the differences between proposed device and predicate device
Guilin Woodpecker D-Laser 16 (To be decided)	**Dentsply Sirona SIROLaser Advance+ (K170500)**	**Dentsply Sirona SIROLaser Advance (K103753)**	**Biolase, Inc Epic Pro (K163128)**	**IRIDEX Corporation Iridex IQ Laser System IQ 630-670 (K071687)**	
190 mm x 180 mm x 200 mm	182 mm x 197 mm x 189 mm	182 mm x 197 mm x 189 mm	184 mm x 114 mm x 165 mm	Unknown	Different size doesn't affect the substantial equivalence with the predicate.
Laser Control Unit User Interface					
Color touch screen graphical user interface	Color touch screen graphical user interface	Color touch screen graphical user interface	Color touch screen graphical user interface	Manual & Remote Controls	/

From above two tables, the proposed device D-Laser Blue and the predicate device SIROLaser Blue, and the proposed device D-Laser 16 and the predicate device SIROLaser Advance+ have the same indications for use respectively. Although there are subtle technological characteristic differences between the proposed devices and their predicate devices, it is clear that the technological characteristic differences discussed do not affect the substantial equivalence.

5.7 Brief discussion of the non-clinical tests

To verify the performance requirements of D-Laser Blue and D-Laser16, the following tests were performed. It shows that the testing results do support substantial equivalence.

- Verify the conformity of the proposed devices with the requirements of IEC 60601-1:(*Medical electrical equipment Part 1: General requirements for basic safety and essential performance*).
- Verify the conformity of the proposed devices with the requirements of IEC 60601-1-2:(*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic compatibility*).
- Verify the conformity of the proposed devices to IEC 60825-1 (*Safety of laser products - Part 1: Equipment classification and requirements*).
- Verify the performance of the proposed devices according to IEC 60601-2-22: *(Medical electrical equipment Part 2: Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment).*
- Conduct usability study in conformity with IEC 62366 (*Medical devices - Application of usability engineering to medical devices*).
- Validate the devices' software in conformity with IEC 62304 (*Medical device software - Software lifecycle processes*).
- Evaluate the biocompatibility of patient contacting components of the proposed devices according to the requirements ISO 10993-5 (Biological evaluation of medical devices Part 5: Test for cytotoxicity).
- Summarize studies conducted utilizing D-Laser 16/D-Laser Blue comparing the cutting efficiency of the predicate device SIROLaser Advance+ /SIROLaser Blue. (Note: D-Laser 16 vs SIROLaser Advance+; D-Laser Blue vs SIROLaser Blue.

5.8 Brief discussion of clinical tests

No human clinical data is needed for D-Laser Blue and D-Laser 16.

5.9 Other information (such as required by FDA guidance/Test)

N/A.

5.10 Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Guilin Woodpecker Medical Instrument Co., Ltd. concludes that:

- The indications for use of D-Laser Blue and D-Laser 16 are totally same as those of the predicate devices.
- The technological characteristic differences between D-Laser Blue and SIROLaser Blue, and between D-Laser 16 and SIROLaser Advance+ do not affect the substantial equivalence, so no new risk is raised.
- Demonstrated by the safety and performance tests, the characteristics of D-Laser Blue and D-Laser 16 are respectively equivalent to those of the predicate devices.