

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 <u>Federal Register</u>.

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-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">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
ndications 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 roughing; 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 issues; 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 necision 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 emporary relaxation of muscles.
Type of Use (Select one or both, as applicable)
Prescription Use (Part 21 CFR 801 Subpart D)
CONTINUE ON A SEPARATE PAGE IF NEEDED.
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Guilin Woodpecker 004_510(k) Summary

Product: D-Laser Blue, D-Laser 16

Version:A/0

004_510(k) Summary

Version:A/0

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: <u>ipr@glwoodpecker.com</u>
Submission Correspondent	Company Name: Shenzhen Joyantech Consulting Co., Ltd.
卓远天成	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	3005581016
number	

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

Product:	D ₋ l ager	Rlue	D-Laser 16
Flouuci.	D-Lasei	Diue.	D-Lasel 10

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

Chanasii	Sirona Dental	Biolase, Inc	Iridex	ILT Systems,
Sponsor:	Systems GmbH		Corporation	Inc.
David	SIROLaser	E.i. D.	10 000 070	401 5500
Device:	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.

Version:A/0

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 interdental 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.

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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		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	1
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	1
Classification						
Class II	Class II	Class II	Class II	Class II	Class II	1
Surgical Indication fo						
Intended for intra-	Intended for intra-	Intended for intra-	Intended for incision,	Indicated for use in	Intended for use in	
and extra-oral	and extra-oral	and extra-oral	excision,	photocoagulation of	dental intraoral soft	
surgery including	surgery including	surgery including	vaporization,	both anterior and	tissue, general, oral	
incision, excision,	incision, excision,	incision, excision,	ablation, hemostasis,	posterior segments	maxilla-facial and	1
hemostasis,	hemostasis,	hemostasis,	or coagulation of	including:	cosmetic surgery. It is	
coagulation and	coagulation and	coagulation and	intraoral and extra-	* Retinal	intended for ablating,	
vaporization of soft	vaporization of soft	vaporization of soft	oral soft tissue	photocoagulation,	incising, excising,	

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tissue including	tissue including	tissue including	(including marginal	panretinal	aporizing and	
marginal and inter-	marginal and inter-	marginal and inter-	and interdental	photocoagulation	coagulation of soft	
dental and epithelial	dental and epithelial	dental and epithelial	gingiva and epithelial	and intravitreal	/tissues using a fiber	
lining of free gingiva	lining of free gingiva	lining of free gingiva	lining of free	endophotocoagulati	optic delivery system.	
and is indicated for:	and is indicated for:	and is indicated for:	gingiva); examples	on of vascular and	The following are the	
			include:	structural	indications for which	
				abnormalities of the	the device will be	
				retina and choroid	marketed:	
				including:		
frenectomy;	frenectomy;	frenectomy;	frenectomy;	> proliferative and	frenectomy;	
frenotomy;	frenotomy;	frenotomy;	frenotomy;	nonproliferative	frenotomy;	1
biopsy;	biopsy;	biopsy;	biopsy;	diabetic	Excision and incision	
operculectomy;	operculectomy;	operculectomy;	operculectomy;	retinopathy;	biopsies;	1
				> choroidal	operculectomy	
implant recovery;	implant recovery;	implant recovery;	implant recovery;	neovascularization;	N/A	1
gingivectomy;	gingivectomy;	gingivectomy;	gingivectomy;	> branch retinal vein	gingivectomy;	
gingivoplasty;	gingivoplasty;	gingivoplasty;	gingivoplasty;	occlusion;	gingivoplasty;	

Proposed Device	Predicate Device			Discussion of the differences between proposed device and predicate device		
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gingival troughing;	gingival troughing;	gingival troughing;	gingival troughing;	> age-related	N/A	1
crown lengthening;	crown lengthening;	crown lengthening;	crown lengthening;	macular	Soft tissue crown	
				degeneration	lengthening	1
hemostasis of donor	hemostasis of donor	hemostasis of donor	hemostasis of donor	> retinal tears and	Hemostatic	,
site;	site;	site;	site;	detachments	assistance	1
removal of	removal of	removal of	removal of	> retinopathy of	N//A	,
granulation tissue;	granulation tissue;	granulation tissue;	granulation tissue;	prematurity	N/A	1
laser assisted flap	laser assisted flap	laser assisted flap	laser assisted flap	* Iridotomy,	N//A	,
surgery;	surgery;	surgery;	surgery;	iridectomy and	N/A	1
debridement of	debridement of	debridement of	debridement of	trabeculoplasty in		
diseased epithelial	diseased epithelial	diseased epithelial	diseased epithelial	angle closure	N/A	1
lining;	lining;	lining;	lining;	glaucoma and open		
incisions and draining	incisions and draining	incisions and draining	incisions and draining	angle glaucoma	incisions and draining	
of abscesses;	of abscesses;	of abscesses;	of abscesses;		of abscesses;	1
tissue retraction for	tissue retraction for	tissue retraction for	tissue retraction for		tissue retraction for	
impressions;	impressions;	impressions;	impressions;		impressions;	1
papillectomy;	papillectomy;	papillectomy;	papillectomy;		Oral papillectomy	1

Proposed Device	Predicate Device		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)	•
vestibuloplasty;	vestibuloplasty;	vestibuloplasty;	vestibuloplasty;			
excision of lesions;	excision of lesions;	excision of lesions;	excision of lesions;		N/A	1
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	1
removal of hyperplastic tissues;	removal of hyperplastic tissues;	removal of hyperplastic tissues;	removal of hyperplastic tissues;		N/A	I
treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers;		treatment of aphthous ulcers;	I
leukoplakia;	leukoplakia;	leukoplakia;	leukoplakia;		N/A	1
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	1
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;	1

Proposed Device	Predicate Device		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	treatment of canker	treatment of canker						
sores; herpetic ulcers	sores; herpetic ulcers	sores; herpetic ulcers	N/A		N/A			
of the oral mucosa;	of the oral mucosa;	of the oral mucosa;						
laser soft tissue curettage;	laser soft tissue curettage;	laser soft tissue curettage;	N/A		N/A	1		
reduction of gingival	reduction of gingival	reduction of gingival						
hypertrophy.	hypertrophy.	hypertrophy.	N/A		N/A	1		
Laser Periodontic Ind	Laser Periodontic Indications for Use							
laser removal of	laser removal of	laser removal of						
diseased, infected,	diseased, infected,	diseased, infected,						
inflamed and	inflamed and	inflamed and						
necrosed soft tissue;	necrosed soft tissue;	necrosed soft tissue;	N/A	N/A	N/A			
within the periodontal	within the periodontal	within the periodontal						
pocket;	pocket;	pocket;						
sulcular debridement	sulcular debridement	sulcular debridement	sulcular debridement		Sulcular debridement			
(removal of diseased,	(removal of diseased,	(removal of diseased,	(removal of diseased	N/A	(removal of diseased	1		
infected, inflamed	infected, inflamed	infected, inflamed	or inflamed soft tissu		or inflamed soft			

Proposed Device	Predicate Device		Reference Devices				
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	and necrosed soft	and necrosed soft	e in the periodontal p		tissue in the		
tissue in the	tissue in the	tissue in the	ocket)		periodontal pocket);		
periodontal pocket to	periodontal pocket to	periodontal pocket to			Photo initiation of		
improve clinical	improve clinical	improve clinical			gingival barriers and		
indices including	indices including	indices including			dams		
gingival index,	gingival index,	gingival index,					
gingival bleeding	gingival bleeding	gingival bleeding					
index, probe depth,	index, probe depth,	index, probe depth,					
attachment loss and	attachment loss and	attachment loss and					
tooth inability);	tooth inability);	tooth inability);					
Tooth Whitening India	cations for Use						
Light activation for	Light activation for		Light activation for		Laser-assisted		
bleaching materials	bleaching materials	N/A	bleaching materials	N/A	bleaching/whitening	1	
for teeth whitening.	for teeth whitening.		for teeth whitening.		of teeth		
laser-assisted	laser-assisted						
whitening/bleaching	whitening/bleaching	N/A	N/A	N/A	N/A	1	
of teeth.	of teeth.						

Proposed Device	Predicate Device		Discussion of the differences between proposed device and predicate device			
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Low Level Laser The	rapy Indications for Use	1				
Intended to emit	Intended to emit					
energy in the red and	energy in the red and					
infrared spectrum to	infrared spectrum to					
provide topical	provide topical					
heating for the	heating for the					
purpose of elevating	purpose of elevating					
tissue temperature	tissue temperature					
for the temporary	for the temporary	N/A	N/A	N/A	N/A	
relief of minor muscle	relief of minor muscle	1471	1471	1471		,
and joint pain and	and joint pain and					
stiffness, minor	stiffness, minor					
arthritis pain, or	arthritis pain, or					
muscle spasm, and	muscle spasm, and					
for the temporary	for the temporary					
increase in local	increase in local					
blood circulation	blood circulation					

Proposed Device	Predicate Device		Discussion of the differences between proposed device and predicate device			
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and/or temporary	and/or temporary					
relaxation of muscles.	relaxation of muscles.					
Application						
Dental Laser	Dental Laser	Dental Laser	Dental Laser	IQ Laser	Curing Laser	1
Laser Classification						
976 nm and 450nm	970 nm and 445 nm	970 nm: Class IV	980 nm: Class IV	630-670 nm	450 nm	According to K180044,
Laser: Class IV	Laser: Class IV					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	660 nm Laser: Class					According to K071687, 650 nm
II	II					can be accepted.
Laser Type						
Solid state diode	Solid state diode	Solid state diode	Solid state diode	Diode, Diode-	Argon Ion	1

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

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

Proposed Device	Predicate Device		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)	·
		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	l Tips				,	

Proposed Device	Predicate Device		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)	·
Fiber Diameter:	Fiber Diameter:	Fiber Diameter:	Fiber Diameter:		Fiber Diameter:	According to K180044 and
200 μm, 300 μm, 400	200 μm, 320 μm	200 μm, 320 μm	• 300 μm, 400 μm	NI/A	400 μm	K163128, all fiber diameters of
μm,				N/A		the proposed device can be
						accepted.
Single-use tips.	Single-use tips.	Single-use tips.	Quartz single-use	Delivery Devices		
Integral laser fiber.	Integral laser fiber.	Laser fiber	tips varying in	provided sterile		
Plastic proximal	Plastic proximal	assembled with tip	length and core	packaged & non-		
connection hub.	connection hub.	by user.	diameter	sterile		
Bendable stainless	Bendable stainless	Plastic proximal	Medical grade			
steel cannula.	steel cannula.	connection hub.	plastics, steel,		N/A	
 Provided non- 	Provided sterile	Bendable stainless	stainless steel,		N/A	1
sterile	(sterilized by	steel cannula.	aluminum, brass,			
	ethylene oxide).	Provided non-	and electronic			
		sterile	parts and			
			components			
			Disposable			

Proposed Device	Predicate Device		Reference Devices				
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)	predicate device	
Handpiece	Handpiece	Handpiece	Handpiece		Disposable, Barrier		
connected by	connected by	connected by	connected by fiber		sleeve		
flexible optical fiber	flexible optical fiber	flexible optical fiber	optic cable,				
to control unit.	to control unit.	to control unit.					
Finger switch laser	Finger switch laser	Finger switch laser					
activation.	activation.	activation.				,	
Removable,	Removable,	Removable,					
sterilizable	sterilizable	sterilizable outer					
stainless steel	stainless steel	sleeve.					
outer sleeve.	outer sleeve.						
Laser Therapy Light 0	Guides						
	Curved light						
N/A	guides;	N/A	N/A	N/A	N/A		
I IVA	• 4 mm, 8mm	11//2	19/73	N/A	I N/A	,	
	diameter.						
Activation Method							
Handpiece finger	Handpiece finger	Handpiece finger	Wireless	Footswitch	FAN forced air	1	

Proposed Device	Predicate Device		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.	switch.	switch.	footswitch.			
 Wireless foot 	Optional wireless	Optional wireless				
switch.	foot switch.	foot switch.				
Laser Control Unit Di	mensions					
190 mm x 180 mm x	182 mm x 197 mm x	182 mm x 197 mm x	184 mm x 114 mm x			Different size doesn't affect the
200 mm	189 mm	189 mm	165 mm	Unknown	Unknown	substantial equivalence with the
						predicate.
Laser Control Unit Us	er Interface					
Color touch screen	Color touch screen	Color touch screen	Color touch screen	Manual & Remote	Discreet switches	
graphical user	graphical user	graphical user	graphical user	Controls		1
interface	interface	interface	interface			

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		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	1
Regulation Number					
21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	1
Classification					
Class II	Class II	Class II	Class II	Class II	1
Surgical Indication for Use	•				
Intended for intra- and	Intended for intra- and	Intended for intra- and	Intended for incision,	Indicated for use in	
extra-oral surgery	extra-oral surgery	extra-oral surgery	excision, vaporization,	photocoagulation of both	
including incision,	including incision,	including incision,	ablation, hemostasis, or	anterior and posterior	
excision, hemostasis,	excision, hemostasis,	excision, hemostasis,	coagulation of intraoral	segments including:	1
coagulation and	coagulation and	coagulation and	and extra-oral soft tissue	* Retinal	
vaporization of soft tissue	vaporization of soft tissue	vaporization of soft tissue	(including marginal and	photocoagulation,	
including marginal and	including marginal and	including marginal and	interdental gingiva and	panretinal	

Proposed Device	Predicate Device		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	inter-dental and epithelial	inter-dental and epithelial	epithelial lining of free	photocoagulation and	
lining of free gingiva and is	lining of free gingiva and is	lining of free gingiva and is	gingiva); examples	intravitreal	
indicated for:	indicated for:	indicated for:	include:	endophotocoagulation of	
				vascular and structural	
				abnormalities of the	
				retina and choroid	
				including:	
frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy;	> proliferative and	1
biopsy; operculectomy;	biopsy; operculectomy;	biopsy; operculectomy;	biopsy; operculectomy;	nonproliferative diabetic	1
implant recovery;	implant recovery;	implant recovery;	implant recovery;	retinopathy;	1
gingivectomy;	gingivectomy;	gingivectomy;	gingivectomy;	> choroidal	
gingivoplasty;	gingivoplasty;	gingivoplasty;	gingivoplasty;	neovascularization;	/
gingival troughing;	gingival troughing;	gingival troughing;	gingival troughing;	> branch retinal vein	1
crown lengthening;	crown lengthening;	crown lengthening;	crown lengthening;	occlusion;	1
hemostasis of donor site;	hemostasis of donor site;	hemostasis of donor site;	hemostasis of donor site;	> age-related macular	1
removal of granulation	removal of granulation	removal of granulation	removal of granulation	degeneration > retinal tears and	
tissue;	tissue;	tissue;	tissue;	r reurial tears allu	/

Proposed Device	Predicate Device		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	laser assisted flap	laser assisted flap	laser assisted flap	detachments	,
surgery;	surgery;	surgery;	surgery;	> retinopathy of	1
debridement of diseased	debridement of diseased	debridement of diseased	debridement of diseased	prematurity	
epithelial lining;	epithelial lining;	epithelial lining;	epithelial lining;	* Iridotomy, iridectomy and	
incisions and draining of	incisions and draining of	incisions and draining of	incisions and draining of	trabeculoplasty in angle	
abscesses;	abscesses;	abscesses;	abscesses;	closure glaucoma and	1
tissue retraction for	tissue retraction for	tissue retraction for	tissue retraction for	open angle glaucoma	
impressions;	impressions;	impressions;	impressions;		1
papillectomy;	papillectomy;	papillectomy;	papillectomy;		
vestibuloplasty;	vestibuloplasty;	vestibuloplasty;	vestibuloplasty;		1
excision of lesions;	excision of lesions;	excision of lesions;	excision of lesions;		1
exposure of	exposure of	exposure of	exposure of		
unerupted/partially	unerupted/partially	unerupted/partially	unerupted/partially		1
erupted teeth;	erupted teeth;	erupted teeth;	erupted teeth;		
removal of hyperplastic	removal of hyperplastic	removal of hyperplastic	removal of hyperplastic		
tissues;	tissues;	tissues;	tissues;		/
treatment of aphthous	treatment of aphthous	treatment of aphthous	treatment of aphthous		
ulcers;	ulcers;	ulcers;	ulcers;		/

Proposed Device	Predicate Device		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;		1
pulpotomy; pulpotomy as	pulpotomy; pulpotomy as	pulpotomy; pulpotomy as	pulpotomy; pulpotomy as		
adjunct to root canal	adjunct to root canal	adjunct to root canal	adjunct to root canal		1
therapy;	therapy;	therapy;	therapy;		
fibroma removal; gingival	fibroma removal; gingival	fibroma removal; gingival	N/A		
incision and excision;	incision and excision;	incision and excision;	N/A		1
treatment of canker sores;	treatment of canker sores;	treatment of canker sores;			
herpetic ulcers of the oral	herpetic ulcers of the oral	herpetic ulcers of the oral	N/A		1
mucosa;	mucosa;	mucosa;			
laser soft tissue curettage;	laser soft tissue curettage;	laser soft tissue curettage;	N/A		1
reduction of gingival	reduction of gingival	reduction of gingival			
hypertrophy.	hypertrophy.	hypertrophy.	N/A		1
Laser Periodontic Indication					
laser removal of diseased,	laser removal of diseased,	laser removal of diseased,			
infected, inflamed and	infected, inflamed and	infected, inflamed and	N/A	N/A	
necrosed soft tissue;	necrosed soft tissue;	necrosed soft tissue;		N/A	/
within the periodontal	within the periodontal	within the periodontal			

Proposed Device	Predicate Device		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	sulcular debridement	sulcular debridement	sulcular debridement (rem		
(removal of diseased,	(removal of diseased,	(removal of diseased,	oval of diseased or inflam		
infected, inflamed and	infected, inflamed and	infected, inflamed and	ed soft tissue in the period		
necrosed soft tissue in the	necrosed soft tissue in the	necrosed soft tissue in the	ontal pocket)		
periodontal pocket to	periodontal pocket to	periodontal pocket to		N/A	
improve clinical indices	improve clinical indices	improve clinical indices		N/A	/
including gingival index,	including gingival index,	including gingival index,			
gingival bleeding index,	gingival bleeding index,	gingival bleeding index,			
probe depth, attachment	probe depth, attachment	probe depth, attachment			
loss and tooth inability);	loss and tooth inability);	loss and tooth inability);			
Tooth Whitening Indication	ns for Use				
Light activation for	Light activation for		Light activation for		
bleaching materials for	bleaching materials for	N/A	bleaching materials for	N/A	1
teeth whitening.	teeth whitening.		teeth whitening.		
Laser-assisted	laser-assisted				
whitening/bleaching of	whitening/bleaching of	N/A	N/A	N/A	1
teeth.	teeth.				

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	Intended to emit energy in				
the red and infrared	the red and infrared				
spectrum to provide	spectrum to provide				
topical heating for the	topical heating for the				
purpose of elevating	purpose of elevating				
tissue temperature for the	tissue temperature for the				
temporary relief of minor	temporary relief of minor				
muscle and joint pain and	muscle and joint pain and	N/A	N/A	N/A	1
stiffness, minor arthritis	stiffness, minor arthritis				
pain, or muscle spasm,	pain, or muscle spasm,				
and for the temporary	and for the temporary				
increase in local blood	increase in local blood				
circulation and/or	circulation and/or				
temporary relaxation of	temporary relaxation of				
muscles.	muscles.				
Application					
Dental Laser	Dental Laser	Dental Laser	Dental Laser	IQ Laser	1

Proposed Device	Predicate Device		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	1
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)	660 nm (+/-5 nm)				According to K071687, 630-
(630-670)	(655-665)				670 nm can be accepted.
Optical Power					
<u>976 nm:</u>	<u>970 nm:</u>	970 nm:	<u>980 nm:</u>	630-670 nm:	According to K163128, the
0.3 W - 7 W	0.2 W - 7.0 W (CW)	7.0 W max.	0.2 W - 25 W	≤ 5W	highest value 25W can be
(Continuous Wave)	14 W (peak optical power)	(Continuous Wave)			accepted, so 0.2 W - 4 W can
16 W (peak power)		14 W (peak optical power)			be accepted.
<u>650 nm:</u>	<u>660 nm:</u>				According to K071687, the
25 mW-200 mW	25 mW, 50 mW, 100 mW				highest value 5 W can be
(Continuous Wave)					accepted. According to
					K170500 and K071687, 25
					mW-200 mW can be accepted.
Emission Modalities					
Continuous Wave	Continuous Wave	Continuous Wave	Pulsed or continuous	CW (CW-Pulse,	According to K163128,
• Chopped (1 Hz - 20	• Chopped (1 Hz - 10	Chopped (1 Hz - 10	(up to 20 kHz)	MicroPulse, Long Pulse)	chopped value can be up to 20
kHz)	kHz)	kHz)		Repetition rate≤ 1kHz	kHz, so the emission modalities

Predicate Device		Discussion of the differences between proposed device and predicate device		
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 -	Peak Pulse (up to 20			of the proposed device can be
20 kHz)	kHz)			accepted.
Chopped Mode: 10 µsec. to 0.99 sec. Peak Pulse Mode: 23 µsec.	Chopped Mode: 10 µsec. To 0.99 sec. Peak Pulse Mode: 23 µsec.	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.
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
	Dentsply Sirona SIROLaser Advance+ (K170500) • Peak Pulse (1.5 kHz - 20 kHz) Chopped Mode: 10 µsec. to 0.99 sec. Peak Pulse Mode: 23 µsec.	Dentsply Sirona SIROLaser Advance+ (K170500) • Peak Pulse (1.5 kHz - 20 kHz) Chopped Mode: 10 μsec. to 0.99 sec. Peak Pulse Mode: 23 μsec. Peak Pulse Mode: 23 μsec. Dentsply Sirona SIROLaser Advance (K103753) • Peak Pulse (up to 20 kHz) Chopped Mode: 10 μsec. To 0.99 sec.	Dentsply Sirona SIROLaser Advance+ (K170500) Dentsply Sirona SIROLaser Advance (K103753) Biolase, Inc Epic Pro (K163128) • Peak Pulse (1.5 kHz - 20 kHz) • Peak Pulse (up to 20 kHz) Chopped Mode: 10 μsec. to 0.99 sec. Chopped Mode: 10 μsec. To 0.99 sec. 10 μsec. to 0.99 sec. 50 ms to 99.9 s Peak Pulse Mode: 23 μsec. μsec. 660±5 nm 635 nm-650 nm 650nm	Dentsply Sirona SIROLaser Advance (K170500) Dentsply Sirona SIROLaser Advance (K170500) (K163128) Dentsply Sirona SIROLaser Advance (K163128) Dentsply Sirona SIROLaser Advance (K163128) Dentsply Sirona Dentsply Sirona SIROLaser Circle Ci

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 Tipe	S				
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		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,		1
Laser Therapy Light Guide	es				
N/A	Curved light guides; 4 mm, 8mm diameter.	N/A	N/A	N/A	1
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	1
Laser Control Unit Dimens		Switch.			

Guilin Woodpecker 004_510(k) Summary

Product: D-Laser Blue, D-Laser 16 Version:A/0

Proposed Device	Predicate Device		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	182 mm x 197 mm x 189	182 mm x 197 mm x 189	184 mm x 114 mm x 165		Different size doesn't affect the
mm	mm	mm	mm	Unknown	substantial equivalence with the
					predicate.
Laser Control Unit User In					
Color touch screen	Color touch screen	Color touch screen	Color touch screen	Manual & Remote	,
graphical user interface	graphical user interface	graphical user interface	graphical user interface	Controls	1

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:

Guilin Woodpecker 004_510(k) Summary

Version:A/0

 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.