May 19, 2026

Shenzhen Soga Technology Co., Ltd.
Zhang Sha
Regulatory Affairs Manager
Room 102, 2nd Floor & Room 302, 3rd Floor, Building 1,
Second Industrial Zone,No. 16, Guanghui Road,
Shenzhen, Guangdong 318110
CHINA

Re: K253309
Trade/Device Name: SOGA Lasers therapy system family of Aurora handpiece (Aurora-S); SOGA Lasers therapy system family of the Dental diode laser (ILaser III Pro)
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, GEX
Dated: September 27, 2025
Received: September 29, 2025

Dear Zhang Sha:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253309

Please provide the device trade name(s).

SOGA Lasers therapy system family of Aurora handpiece (Aurora-S);
SOGA Lasers therapy system family of the Dental diode laser (ILaser III Pro)

Please provide your Indications for Use below.

Aurora-S:
• Intra-oral soft tissue surgery (incision, excision, ablation, coagulation);
• Leukoplakia;
• Pulpotomy as adjunct to root canal retreatment;
• Pulp extirpation;
• Removal of fibromae;
• Removal of granulated tissue;
• Caries removal, cavity preparation, enamel roughening;
• Sulcular debridement;
• Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement;
• Cutting, shaving, contouring and resection of oral osseous tissue (bone);
• Osteotomy, osseous crown lengthening, osteoplasty;
• Apicectomy surgery;
• Removal of subgingival calculus in periodontal pockets with periodontitis by closed or open curettage;
• Laser removal of porcelain and ceramic crowns and veneers;
• Flap preparation – incision of soft-tissue to prepare a flap and expose the bone;
• Cutting bone to prepare a window access to the apex (apices) of the root(s);
• Root-end preparation for retrofill amalgam or composite;
• Full thickness flap;
• Partial thickness flap;
• Split thickness flap;
• Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket;
• Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium;
• Excisional and incisional biopsies;
• Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions);
• Frenectomy and frenotomy;
• Gingival troughing for crown impressions;
• Gingivectomy;
• Gingivoplasty;
• Implant recovery;
• Root canal debridement and cleaning;
• Soft tissue crown lengthening;
• Laser root canal disinfection after endodontic treatment

ILaser III Pro:
SOGA Lasers therapy system family of the Dental diode laser is intended for intra-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 sulcus periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; herpetic ulcers of the oral mucosa; laser soft tissue curettage.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary K253309

1. Administrative Information

Date of Summary prepared: September 27,2025

1.1 Submitter Information

- Company: Shenzhen SOGA Technology Co., Ltd.
- Address: Room 102, 2nd Floor & Room 302, 3rd Floor, Building 1, Second Industrial Zone, No. 16, Guanghui Road, Longteng Community, Shiyan Street, Bao'an District, Shenzhen, Guangdong Province, China.
- Phone: +086-18801027360
- Contact: Lisa, zhang, Regulatory Affairs Manager
- Mail box: zhangs@soga12.com

1.2 Device Information

- Common Name: SOGA Lasers therapy system family
- Trade/Device Name: SOGA Lasers therapy system family of the Dental diode laser, SOGA Lasers therapy system family of Aurora handpiece
- Model: ILaser III Pro、Aurora-S
- Classification regulation: Laser, Dental, Soft Tissue
- Regulation number: 21 CFR 878.4810
- Regulation Description: Laser surgical instrument for use in general and plastic surgery and in dermatology Medical
- Regulation Medical Specialty: General & Plastic Surgery
- Review Panel: Dental
- Product Code: NVK GEX
- Device Class: Class II
- Submission number: Not assigned.

1.3 Predicate Devices and Reference Devices

Model: Aurora-S

/	**Predicate Device**	**Reference device**
Sponsor:	**Fotona.d.o.o.**	**Guilin Woodpecker Medical Instrument Co., Ltd.**
Device:	LightWalker Laser System Family	D-Laser Blue
510(K) Number	K242202	K210367

Model:ILaser III Pro

Predicate Devices

Sponsor:	**Guilin Woodpecker Medical Instrument Co., Ltd.**

Sponsor:	Guilin Woodpecker Medical Instrument Co., Ltd.
Device:	D-Laser Blue
510(K) Number	K210367

1.4 Device Description

Model :Aurora-S

The SOGA Lasers Therapy System Family (equipped with Aurora Handpiece) is based on Er:YAG (2940 nm) and multi-wavelength diode laser (450 nm, 650 nm, 980 nm) technology.

Laser Generation Mechanism

Er:YAG Laser (2940 nm): Utilizes Er:YAG crystal as the solid-state working medium. Activated particles in the crystal absorb specific wavelength light energy (via diode-pumped excitation), inducing particle population inversion and laser emission.

Diode Lasers (450 nm, 650 nm, 980 nm): Adopt doped semiconductor diode materials as the laser medium. Natural cleavage surfaces of the diode form resonant cavities, and resonant amplification of these cavities achieves stimulated feedback, realizing directional, stable laser output .

Beam Integration and Transmission

Both therapeutic laser beams (Er:YAG and diode lasers) are coupled into a flexible fiber optic cable and transmitted to the Aurora Handpiece tip. Disposable fiber optic tips (accessories) attach to the handpiece distal end to optimize beam shaping and target tissue delivery.

Control and Operation System

Output Control: Laser energy emission is regulated by a foot switch assembly, ensuring hands-free operation during treatment.

Human-Machine Interface: A touchscreen displays real-time operational status (e.g., wavelength selection, power parameters) and treatment modes. Users select protocols, adjust system settings, and confirm parameters via touch input, achieving intuitive control of the dual laser system .

It integrates dual laser generation modules, power supply, control device, laser transmission components, and cooling system within a single enclosure, forming an integrated therapeutic platform .

Model: ILaser III Pro:

The main components of ILaser III Pro are dental diode lasers with wavelengths of 450nm, 650nm, and 980nm. The semiconductor laser diode is excited by the generation power supply to generate the laser, which is effectively transmitted to the treatment site through the optical fiber tip.

1.5 Indications for Use

NO.	Aurora-S	ILaser III Pro
1	Intra-oral soft tissue surgery (incision, excision, ablation, coagulation)	frenectomy frenotomy
2	Leukoplakia	biopsy operculectomy
3	Pulpotomy as adjunct to root canal retreatment	implant recovery
4	Pulp extirpation	gingivectomy gingivoplasty

NO.	**Aurora-S**	**ILaser III Pro**
5	Removal of fibromae	gingival troughing
6	Removal of granulated tissue	crown lengthening
7	Caries removal, cavity preparation, enamel roughening	hemostasis of donor site
8	Sulcular debridement	removal of granulation tissue
9	Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement	laser assisted flap surgery
10	Cutting, shaving, contouring and resection of oral osseous tissue (bone)	debridement of diseased epithelial lining
11	Osteotomy, osseous crown lengthening, osteoplasty	incisions and draining of abscesses
12	Apicectomy surgery	tissue retraction for impressions
13	Removal of subgingival calculus in periodontal pockets with periodontitis by closed or open curettage	papillectomy vestibuloplasty
14	Laser removal of porcelain and ceramic crowns and veneers	excision of lesions
15	Flap preparation – incision of soft-tissue to prepare a flap and expose the bone	exposure of unerupted/partially erupted teeth
16	Cutting bone to prepare a window access to the apex (apices) of the root(s)	removal of hyperplastic tissues
17	Root-end preparation for retrofill amalgam or composite	treatment of aphthous ulcers
18	Full thickness flap	leukoplakia
19	Partial thickness flap	pulpotomy pulpotomy as adjunct to root canal therapy
20	Split thickness flap	fibroma removal
21	Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket	gingival incision and excision
22	Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium	treatment of canker sores
23	Excisional and incisional biopsies	herpetic ulcers of the oral mucosa
24	Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)	laser soft tissue curettage
25	Frenectomy and frenotomy	reduction of gingival hypertrophy.
26	Gingival troughing for crown impressions	laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
27	Gingivectomy	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)
28	Gingivoplasty	/
29	Implant recovery	/

NO.	**Aurora-S**	**ILaser III Pro**
30	Root canal debridement and cleaning	/
31	Soft tissue crown lengthening	/
32	Laser root canal disinfection after endodontic treatment	/

1.6 Comparison with Predicate Decision

1.6.1 Comparison of the Indications for Use

Table 1 Comparison Between the Indications for Use and Technological Characteristics of **Aurora-S** and those of the Predicate and Reference Devices

Proposed Device	**Predicate Device**	**Reference Device**	**Discussion of the differences between proposed device and predicate device**
Shenzhen SOGA Technology Co., Ltd.	**Fotona.d.o.o.**	**Guilin Woodpecker Medical Instrument Co., Ltd.**	/
Product Code			
NVK, GEX	GEX	NVK, GEX, ILY	
Aurora-S	LightWalker Laser System Family	D-Laser Blue	/
Regulation Number			
21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	
Classification			
Class II	Class II	Class II	
Surgical Indication for Use			
Intended for the incision, excision, cutting, ablation, and vaporization of soft and hard tissues in dental and oral surgery, and dentistry.	Er:YAG laser (2940 nm wavelength) in dentistry:	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 is indicated for:	/
Leukoplakia	Leukoplakia	Leukoplakia	/

Pulpotomy as adjunct to root canal retreatment	Pulpotomy as adjunct to root canal retreatment	Pulpotomy as adjunct to root canal retreatment	/
Pulp extirpation	Pulp extirpation	N/A	/
Removal of fibromae	Removal of fibromae	Fibroma removal	/
Removal of granulated tissue	Removal of granulated tissue	Removal of granulation tissue	/
Caries removal, cavity preparation, enamel roughening	Caries removal, cavity preparation, enamel roughening	N/A	/
Sulcular debridement	Sulcular debridement	Sulcular debridement	/
Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement	Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement	N/A	/
Cutting, shaving, contouring and resection of oral osseous tissue (bone)	Cutting, shaving, contouring and resection of oral osseous tissue (bone)	N/A	/
Osteotomy, osseous crown lengthening, osteoplasty	Osteotomy, osseous crown lengthening, osteoplasty	N/A	/
Apicectomy surgery	Apicectomy surgery	N/A	/
Removal of subgingival calculus in periodontal pockets with periodontitis by closed or open curettage	Removal of subgingival calculus in periodontal pockets with periodontitis by closed or open curettage	N/A	/
Laser removal of porcelain and ceramic crowns and veneers	Laser removal of porcelain and ceramic crowns and veneers	N/A	/
Flap preparation – incision of soft-tissue to prepare a flap and expose the bone;	Flap preparation – incision of soft-tissue to prepare a flap and expose the bone;	N/A	/
Cutting bone to prepare a window access to the apex (apices) of the root(s)	Cutting bone to prepare a window access to the apex (apices) of the root(s)	N/A	/

Root-end preparation for retrofill amalgam or composite	Root-end preparation for retrofill amalgam or composite	N/A	/
Full thickness flap	Full thickness flap	N/A	/
Partial thickness flap	Partial thickness flap	N/A	/
Split thickness flap	Split thickness flap	N/A	/
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	/
Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium	Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium	N/A	/
Excisional and incisional biopsies	Excisional and incisional biopsies	N/A	/
Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)	Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)	N/A	/
Frenectomy and frenotomy	Frenectomy and frenotomy	Frenectomy and frenotomy	/
Gingival troughing for crown impressions	Gingival troughing for crown impressions	Gingival troughing	/
Gingivectomy	Gingivectomy	Gingivectomy	/
Gingivoplasty	Gingivoplasty	Gingivoplasty	/
Implant recovery	Implant recovery	Implant recovery	/
Root canal debridement and cleaning	Root canal debridement and cleaning	N/A	/
Soft tissue crown lengthening	Soft tissue crown lengthening	N/A	/
Laser root canal disinfection after endodontic treatment	Laser root canal disinfection after endodontic treatment	N/A	/

Table 2 Comparison Between the Indications for Use of **ILaser III Pro** and those of the Predicate device.

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Proposed Device	Predicate Device	Discussion of the differences between proposed device and predicate device
Shenzhen SOGA Technology Co., Ltd.	**Guilin Woodpecker**	
ILaser III Pro	D-Laser Blue	
Surgical Indication for Use		
Intended for intraand 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 is indicated for:	Intended for intraand 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 is indicated for:	SAME
frenectomy; frenotomy;	frenectomy; frenotomy;	SAME
biopsy; operculectomy;	biopsy; operculectomy;	SAME
implant recovery;	implant recovery;	SAME
gingivectomy; gingivoplasty	gingivectomy; gingivoplasty	SAME
gingival troughing;	gingival troughing;	SAME
crown lengthening;	crown lengthening;	SAME
hemostasis of donor site;	hemostasis of donor site;	SAME
removal of granulation tissue;	removal of granulation tissue;	SAME
laser assisted flap surgery;	laser assisted flap surgery;	SAME
debridement of diseased epithelial lining;	debridement of diseased epithelial lining;	SAME
incisions and draining of abscesses;	incisions and draining of abscesses;	SAME

Proposed Device	Predicate Device	Discussion of the differences between proposed device and predicate device
tissue retraction for impressions;	tissue retraction for impressions;	SAME
papillectomy; vestibuloplasty;	papillectomy; vestibuloplasty;	SAME
excision of lesions;	excision of lesions;	SAME
exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;	SAME
removal of hyperplastic tissues;	removal of hyperplastic tissues;	SAME
treatment of aphthous ulcers;	treatment of aphthous ulcers;	SAME
leukoplakia;	leukoplakia;	SAME
pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as adjunct to root canal therapy;	SAME
fibroma removal;	fibroma removal; gingival	SAME
gingival incision and excision;	gingival incision and excision;	SAME
treatment of canker sores;	treatment of canker sores;	SAME
herpetic ulcers of the oral mucosa;	herpetic ulcers of the oral mucosa;	SAME
laser soft tissue curettage;	laser soft tissue curettage;	SAME
reduction of gingival hypertrophy.	reduction of gingival hypertrophy.	SAME
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;	SAME
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,	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)	SAME

Proposed Device	Predicate Device	Discussion of the differences between proposed device and predicate device
attachment loss and tooth inability)		
Tooth Whitening Indications for Use		
/	light activation for bleaching materials for teeth whitening	The device has no indications for whitening
	laser-assisted whitening/bleaching of teeth	
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 spasms, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	The device has no indications for Therapy

1.6.2 Comparison of the technological characteristics

Table 3 Comparison Between the Technological Characteristics of **Aurora-S** and those of the Predicate and Reference Devices

Item	Proposed Device: SOGA Lasers therapy system family (Model: Aurora-S)		Predicate Device:LightWalker Laser System Family (K242202)	Reference Devices (Model: D-Laser Blue) (K210367)	Discussion of the differences between proposed device and predicate device
User Interface	**Touchscreen**		**Touchscreen**	**Touchscreen**	**SAME**
Laser Type	**Er: YAG laser**	**Diode laser**	**Er: YAG laser**	**Diode laser**	**SAME**
Wavelength	2940 nm	450±20nm 650±20nm 980±20nm	2940 nm	980±20nm 650 nm±20nm 450 nm±10nm	**SAME**

Laser output Mode	Pulsed		Pulsed	Pulsed	**SAME**
Pulse Width	25µs-1000µs	5µs to 0.9s	0.025 – 1 ms	5µs – 0.9 s	**SAME**
Pulse Frequency	Up to 50Hz	1Hz~20kHz	Up to 50 Hz	1Hz~20kHz	**SAME**
Power	Up to 8W	980nm: 0.2 W -4W (Continuous Wave) 7 W (peak power)	Up to 20 W	**976 nm: 0.2 W - 4 W (Continuous Wave) 7 W (peak power)**	The proposed device is within the predicate device.
		650nm: 25 mW -200mW (Continuous Wave)		**650 nm: 25 mW-200 mW (Continuous Wave)**	
		450nm: 0.2W -3.0mW (Continuous Wave) 4 W (peak power)		**450 nm: 0.2 W - 3.0 W (Continuous Wave) 4 W (peak power)**	
Pulse energy	Up to 500mJ	N/A	Up to 1.5 J	N/A	The proposed device is within the predicate device and reference device.

Beam Delivery	Fiber optic tip	Articulated Arm	Optical Fiber Surgical Tips	1.Fiber optic tip is equal to Optical Fiber Surgical Tips , It's just a difference in naming ; 2.Although Fiber optic tip is different from Articulated Arm, the core function of both is to transfer the laser energy from the laser generator to the treatment area without directional deviation. Both can prevent the leakage of erbium laser energy and are compatible with the host and treatment handheld device.
User interface	Touchscreen	Touchscreen	Color touch screen graphical user interface	SAME
Operating system	Windows	Windows	Windows	SAME

Table 4 Comparison Between the Technological Characteristics of **ILaser III Pro** and those of the Predicate Device

Item	Proposed Device	Predicate Device	Discussion of the differences between proposed device and predicate device
510(k) Number	/	K210367	/
Model	ILaser III Pro	D-Laser Blue	
Product Code	NVK, GEX	NVK, GEX, ILY	
Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME

Number			
Classification	II	II	SAME
Application	Dental laser	Dental laser	SAME
Laser Classification	980 nmand 450nm Laser: Class IV 650 nm Laser: Class II	976 nm and 450nm Laser: Class IV 650 nm Laser: Class II	SAME
Laser Type	Solid state diode	Solid state diode	SAME
Laser Wavelength	980±20nm 650 nm±20nm 450 nm±10nm	976 nm (+/-20 nm) (956-996) 650 nm (+/-20 nm) (630-670) 450 nm (+/-20 nm) (430-470)	SAME
Optical Power	980nm: 0.2 W -4W (Continuous Wave) 7 W (peak power) 650 nm: 25 mW-200 mW (Continuous Wave) 450 nm: 0.2 W -3.0 W (Continuous Wave) 4 W (peak power)	976nm: 0.2 W -4 W (Continuous Wave) 7 W (peak power) 650 nm: 25 mW-200 mW (Continuous Wave) 450 nm: 0.2 W -3.0 W (Continuous Wave) 4 W (peak power)	SAME
Emission Modalities	Continuous Wave; 1 Hz – 20 kHz	Continuous Wave; 1 Hz – 20 kHz	SAME
Pulse Duration	5us – 0.9s	5us – 0.9s	SAME
Aiming Beam	650±20 nm, Pmax< 5 mW	650±20 nm, Pmax< 5 mW	SAME
Optical Fiber Surgical Tips			
Fiber Diameter:	0.2mm+0.1mm,0.4mm+0.1 mm	200 μm, 300 μm, 400 μm,	SAME

Item	Proposed Device	Predicate Device	Discussion of the differences between proposed device and predicate device
Surgical Tips	Single-use tips. Provided non sterile	Single-use tips. Provided non sterile	SAME
User Interface	Color touch screen graphical user interface	Color touch screen graphical user interface	SAME
Activation Method	Handpiece finger switch	Handpiece finger switch; Footswitch	Difference, analysis 1 The difference could refer to the Usability testing report and IEC60601-1 testing report.
Delivery System	Fiber optic cable, handpiece, accessories.	Fiber optic cable, handpiece, accessories.	SAME
Laser Control Unit Dimensions	220mm x 277mm x 168mm	190 mm x 180 mm x 200 mm	The minor difference could affect the safety and performance.

2. Brief discussion of the non-clinical tests

To verify the performance requirements of Aurora-S and ILaser III Pro, 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)and IEC TR 60601-4-2:2016(Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems).

- 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 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process).

- Validate the devices' Reprocessing of the proposed device according to ISO 17664 -1 (Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices) and ISO 17665 (Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices)

- Perform the performance testing ;

3. Clinical Testing Performed
No clinical testing was performed.

4. Other information (such as required by FDA guidance/Test)
N/A

5.Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shenzhen soga Technology Co.,LTD. concludes that:

- The indications for use of Aurora-S and ILaser III Pro are totally same as those of the predicate devices.
- The technological characteristic differences between Aurora-S and LightWalker Laser System Family, and between and ILaser III Pro and D-Laser Blue do not affect the substantial equivalence, so no new risk is raised.
- Demonstrated by the safety and performance tests, the characteristics of Aurora-S and ILaser III Pro are respectively equivalent to those of the predicate devices.