May 10, 2022

Shenzhen Soga Technology Co., Ltd.
Tse Adrian
Quality Manager
D906, Yinxing Technology Building No. 1301, Sightseeing Road
Xinlan Community, Guanlan Street, Longhua District
Shenzhen, Guangdong 518110
CHINA

Re: K214008
Trade/Device Name: Dental diode laser
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: March 11, 2022
Received: March 11, 2022

Dear Tse Adrian:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K214008

Device Name
Dental Diode Laser

Indications for Use *(Describe)*

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue; marginal and interdental gingival and epithelial lining of free gingiva; 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 deseased 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;.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

005_510(k) Summary

5.1 Submitter Information

- Company: Shenzhen Soga technology Co., Ltd.
- Address: D906, Yinxing Technology Building No. 1301, Sightseeing Road, Xinlan Community, Guanlan Street, Longhua District, Shenzhen, Guangdong, China.
- Phone: +086-15915873605
- Contact: Tse Adrian, Quality Manager
- Mail box: 15915873605@Soga12.com
- Website: www.soga12.com

5.2 Device Information

- Trade/Device Name: Dental diode laser
- Model: ILaser I
- Common Name: Dental diode laser
- Classification regulation:
  Regulation number: 21 CFR 878.4810
  Regulation Description: Manual surgical instrument for general use.
  Regulation Medical Specialty: General & Plastic Surgery
- Review Panel: General & Plastic Surgery
- Product Code: Primary product code: NVK; Secondary product code: GEX
- Regulation Number: 21 CFR 878.4810
- Device Class: Class II

5.3 Predicate Device Information

Predicate Device: SIROLaser Advance (Model: FonaLaser)

Manufacturer: Sirona Dental Systems GmbH

510(k) number: K103753

Indication of use:

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue; marginal and interdental

gingival and epithelial lining of free gingiva; 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 deseased 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;.

5.4 Device Description

Principle: 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.

Intended operator: Dental surgeon.

Component part: It is composed of laser host (including internal power system, laser drive system, optical path system, LCD screen, emergency stop button, laser) and optic fiber tip.

Sterile: The device mainframe not supplied sterile and do not require sterilization prior to use. The consumable component (Fiber optic tip) not supplied sterile but require sterilization prior to use.

Sterilization condition: 121°C (250°F), 30min

5.5 Indications for Use

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue; marginal and interdental gingival and epithelial lining of free gingiva; 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 deseased 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;.

5.6 Comparison of Technological Characteristics with the Predicate Device

Comparison Items	**Subject Device: SOGALaser (Model: ILaser I)**	**Predicate Device: SIROLaser Advance Model: FONALaser (K103753)**
Classification & Intended Use		
Classification	GEX, NVK Class II 21 CFR 878.4810	GEX Class II 21 CFR 878.4810
Intended use	Intra- and extra-oral surgery including incision, excision, hemostasis,	Intra- and extra-oral surgery including incision, excision, hemostasis,

	coagulation and vaporization of soft tissue; marginal and interdental gingival and epithelial lining of free gingiva; 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 deseased 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,	coagulation and vaporization of soft tissue; marginal and interdental gingival and epithelial lining of free gingiva; 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 deseased 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

	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;.	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;.
Patient Population	For use in all patients	For use in all patients
Environment of Use	For Dental surgeon	Prescription Use - For professional
Patient Population	No restriction on the applicable population	All Population
Comparison Statement	The subject device enjoys the same classification and intended use with the predicate device.	
Technological Characteristics		
Principle / Method of Operation	The semiconductor laser diode is excited by the generation power supply to generate the laser, which is effectively transmitted to	It is generated by a laser diode in the control unit and is guided through a quartz fiber to the treatment area. The laser

	the treatment site through the fiber optic tip.	radiation is absorbed by the tissue and converted into heat for cutting, solidification, bacteria reduction and desensitization.
Environment of Use	Hospital, clinic, and medical office setting	Hospital, clinic, and medical office setting
Size	18cm x 16cm x 26cm	182 x 197 x 189 mm
Shipping list	The product is composed of: ● Mainframe ● Fiber optic tip ● Charging adaptor ● Fiber optic cleaner ● Fiber bender ● Laser area symbol ● Protection glasses	● FONALaser mainframe including A control unit including a handpiece with a manual switch ● Handpiece cover ● Fiber head pack (including 1 x 200 μm and 4 x 320 μm) ● Fiber cutter ● Disposable operation head (including a bending tool) ● Protection glasses ● Switch power supply
Software	MCU software	MCU software
Laser Class	IV (4)	IV (4)
Wavelength	980nm ±20nm	970 nm ± 15nm
Frequency	1Hz to 100Hz	1Hz to 100Hz
Output Power	4.0 W Max CW / 8.0 W	4.0 W Max CW / 7.0 W

	Peak Power (Pulse Mode)	Peak Power (Pulse Mode)
Pulse mode	Continuous	Continuous
Aiming Beam	Laser diode, 5 mW, 680nm±20nm, Class 1	Laser diode, max 1 mW, 635-650nm, Class 1
N.O.H.D.	3.03 meters	1.5 meters
Comparison statement	The subject device has almost the same technological characteristics with the predicate device, and their slight difference in Size, Aiming Beam, Wavelength and N.O.H.D. will not affect the core usage of the devices or validated by relevant standard evaluation or not bringing new safety and effectiveness concerns, thus will not affecting the substantial equivalence comparison. their differences are not affecting the core usage of the devices The difference in Wavelength had verified the safety characteristics by IEC 60825-1 and IEC 60601-2-22, and the efficiency of subject device is better than predicate device. It could be found in literature referred.[1]	
Material Characteristics		
Application part	Fiber optic tip	Fiber
Enclosure	ABS	Not know
Hand piece Cover	Silica gel	elasto-plastic
Safety & Effectiveness		
Patient-Contacting Materials	Fiber optic tip	Fiber
Electrical Safety	Verified according IEC 60601-1	Not know
EMC	Verified according IEC 60601-1-2	Not know

Performance Safety	Verified according IEC 60825-1 and IEC 60601-2-22	Not know
Comparison statement	The safety and essential effectiveness of the subject device have been evaluated according to the FDA recognized standards.	
[1] Robert, A., Convissar. Principles and Practice of Laser Dentistry: 2/E[M]. America: ELSEVIER 2019: 22 p.30. [2] IEC 60825-1: 2014, Annex A.		

5.6.1 Comparison summary

First, the subject device (Model: ILaser I) enjoys identical classification and intended use with the predicate device, which forms the foundation of their substantial equivalence.

Secondly, the most technological characteristics have substantial equivalence difference is below:

Difference item
Shipping list
Size
Wavelength
Aiming Beam
Frequency
Output power
N.O.H.D.
Enclosure material
Handpiece cover material

5.7 Discussion of Tests Performed

5.7.1 Clinical Test

Clinical testing was not performed for SOGALaser (Model: ILaser I) as part of the submission.

5.7.2 Non-Clinical Tests

The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:

	Standard Designation Number	**Title of Standard**
Electrical Safety	IEC 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
Electromagnetic Compatibility	IEC 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
Performance Safety and Effectiveness	IEC 60825-1	Safety of laser products - Part 1: Equipment classification, and requirements
	IEC 60601-2-22	Medical electrical equipment - Part 2-22:

		Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

5.8 Conclusion

From the above analysis, it is proper to conclude that the subject device (Model: ILaser I) will be as safe and effective for usage as the listed predicate devices that have already been on the U.S. market.

5.9 Release date

Apr. 11, 2022