July 1, 2022

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

Re: K211150
Trade/Device Name: Dental diode laser, SOGA Laser, ILaser II
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
Dated: June 21, 2022
Received: June 21, 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)*
K211150

Device Name
Dental Diode Laser, SOGA Laser, ILaser II

Indications for Use *(Describe)*
Dental Soft Tissue Indications:
Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakcia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
- Vestibuloplasty
- Tissue retraction for impression

Laser Periodontal Procedures, including:

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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005_510(k) Summary K211150

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, SOGALaser
- Model: ILaser II
- Common Name: Dental diode laser
- Classification regulation:
  Regulation number: 21 CFR 878.4810
  Regulation Description: Laser surgical instrument for use in general and plastic surgery and in dermatology
  Regulation Medical Specialty: General & Plastic Surgery
- Review Panel: General & Plastic Surgery
- Product Code: GEX
- Regulation Number: 21 CFR 878.4810
- Device Class: Class II
- Submission number: K211150

5.3 Predicate Device Information

Primary Predicate Device: iLase™

Manufacturer: Biolase Technology, Inc.

510(k) number: K093852

Indication of use:

Dental Soft Tissue Indications:

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakcia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
- Vestibuloplasty
- Tissue retraction for impression

Laser Periodontal Procedures, including:

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket

- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).

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 Fiber optic tip and the handpiece cover require sterilization prior to use.

5.5 Indications for Use

Dental Soft Tissue Indications:

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
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5.6 Comparison of Technological Characteristics with the Predicate Device

Comparison Items	**Subject Device: SOGALaser (Model: ILaser II)**	**Predicate Device 1: Dental diode laser (K093852)**
Classification & Intended Use		
Classification	GEX Class II	GEX Class II

	21 CFR 878.4810	21 CFR 878.4810
Intended use	Intended to incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva.	Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications: (For specific refer to Attachment E)
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 the treatment site through the optical fiber treatment head.	The energy is delivered to the treatment site via a single-use fiber optic tip assembly.
Environment of Use	Hospital, clinic, and medical office setting	Hospital, clinic, and medical office setting
Size	φ18mmx200mm	20.5 cm Xφ 1.90 cm
Shipping list	• Main body, • Wireless power supply, • Fiber optic tip, • Laser Safety Glasses (Clinician), • Laser Safety Glasses (Patient), • Cleaning pen, • Silicon cover. • Instruction	• iLase Main Body, • Power Supply – Charging Station, • iLase Cover, • iLase Rechargeable Battery,

		● Tip Initiation Blocks, ● Laser Safety Glasses (Clinician), ● Laser Safety Glasses (Patient), ● iLase Cleaning Kit, ● User Manual
Software	MCU software	MCU software
Laser Class	IV (4)	IV (4)
Wavelength	980nm ±20nm	940 nm ± 10nm
Output Power	3.0 W Max CW / 5.0 W Peak Power (Pulse Mode)	3.0 W Max CW / 5.0 W Peak Power (Pulse Mode)
Power Accuracy	± 5%	± 20%
Pulse mode	Continuous	Continuous
Duty cycle	9.09%~83.3%	9.09%~83.3%
Aiming Beam	Laser diode, max 2 mW,	Laser diode,

	650nm±20nm, Class 1	max 1 mW, 625-670nm, Class 1
N.O.H.D.	3.03 meters	2.61 meters
Comparison statement	The subject device has almost the same technological characteristics with the predicate device, and their slight difference in size, Aiming Beam and Power Accuracy 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 verified the safety characteristics by IEC 60825-1 and IEC 60601-2-22, and the efficiency of the subject device was able to reach an equivalence level of the predicate device. It could be found in the literature referred.[1]	
Material Characteristics		
Application part	Fiber optic	Fiber optic
Enclosure	316L Stainless steel	Not know
Cover	Silica gel	Metal
Safety & Effectiveness		
Patient-Contacting Materials	Fiber optic	Fiber optic
Electrical Safety	Verified according to IEC	Not know

	60601-1	
EMC	Verified according to IEC 60601-1-2	Not know
Performance Safety	Verified according to IEC 60825-1 and IEC 60601-2-22	Not know
Biocompatibility	Verified according to ISO 10993-5 and ISO 10993-10	Not know
Comparison statement	The substantial equivalence of the subject device has 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 II) 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
Wavelength
Power Accuracy
Aiming Beam
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 II) 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 substantial equivalence:

	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	IEC 60825-1	Safety of laser products - Part 1:

Effectiveness		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
Biocompatibility	ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity
	ISO 10993-10	Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization

5.8 Conclusion

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

5.9 Date the Summary was prepared:

June 30, 2022