February 28, 2024

Shanghai Wonderful Opto-Electrics Tech Co., Ltd.
% Fu Ailing
Consultant
Aisnwei Information Technology Co., Ltd.
5F, Block 82, Zhangkeng 2nd Community, Minzhi Street,
Longhua District
Shenzhen, Guangdong 518109
CHINA

Re: K232885
Trade/Device Name: Dawn Diode Laser System
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, EEG
Dated: October 10, 2023
Received: October 16, 2023

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232885

Device Name

Dawn Diode Laser System

Indications for Use *(Describe)*

450 nm, 635 nm and 980 nm Diode Laser:

• Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening:

• Indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy:

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

810 nm Diode Laser in dentistry:

• Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, ophthalmology, and pulmonology
• Oral/Maxillofacial Indications; Incision, excision, vaporization, ablation and/or coagulation of soft tissue
• Gingival troughing for crown impression
• Gingivectomy
• Gingivoplasty
• Gingival incision and excision
• Hemostasis and coagulation
• Excisional and incisional biopsies
• Fibroma removal
• Frenectomy and frenotomy
• Oral papillectomies
• Soft tissue crown lengthening
• Treatment of aphthous ulcers
• Treatment of herpetic lesions
• Periodontology;
• Laser soft tissue curettage
• Laser soft tissue curettage
• Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket

- Cosmetic Dentistry;
- Laser-assisted bleaching/whitening of the teeth
- Light activation for bleaching materials for teeth whitening
- Implant recovery

810 nm Diode Laser in therapy:

- Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

1064 nm Diode Laser in dentistry:

- Excisional and incisional biopsies;
- Excision and vaporization of herpes simplex I and II;
- Frenectomy and frenotomy;
- Gingivectomy;
- Gingivoplasty;
- Gingival incision and excision;
- Hemostasis;
- Implant recovery;
- Operculectomy;
- Pulpotomy and pulpotomy as an adjunct to root canal therapy;
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy;
- Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility);
- Treatment of aphthous ulcers and herpetic lesions

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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510(k) Summary-K232885

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	May 27, 2023
Manufacturer information	Submitter's Name: Shanghai Wonderful Opto-Electrics Tech Co., Ltd. Address: 2F, Building 11, Lane 1175, Tongpu Rd., Putuo District, Shanghai, 200333 China Contact person: Lily Zhou Mobile phone: +86-13701883482 Mail: laser@wonderful-sh.com
Submission Correspondent	Company Name: Aisnwei Information Technology Co., Ltd. Address: 5F, Block 82, Zhangkeng 2nd Community, Minzhi Street, Longhua District, Shenzhen, 518109 China Contact person: Ms. Fu Ailing Mobile phone: +86-13538216349 E-Mail: fuailing@aisnwei.com
Establishment registration number	3004505220

5.2 Device Information

Type of 510(k) submission:	Traditional
Common Name:	Dawn Laser
Trade Name:	Dawn Diode Laser System
Model:	Dawn
Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Review Panel:	General & Plastic Surgery
Primary Product Code:	NVK
Secondary Product Codes	GEX, ILY

Device Class:	II
Regulation Number:	21 CFR 878.4810

5.3 Predicate Devices and Reference Devices

Predicate device	510(k) number: K210367 Trade name: D-Laser Blue, D-Laser 16 Product code: NVK, ILY, GEX
	510(k) number: K221712 Trade name: Fotona XPulse Laser System Family (XPulse 1064 nm, XPulse 810 nm, XPulse 980 nm Product code: GEX
Reference device	510(k) number: K071687 Trade name: Family of IRIDEX® IQ Laser System (IQ532, IQ577, IQ 630-670, IQ810) Product code: GEX
	510(k) number: K163128 Trade name: Epic Pro Product code: GEX
	510(k) number: K111643 Trade name: Opto Mitra Yellow Laser Product code: GEX
	510(k) number: K202991 Trade name: Fotona XPulse Pro Laser Platform Product code: GEX
	510(k) number: K222701 Trade name: MANTA Laser Product code: GEX

5.4 Device Description

The Dawn Diode Laser System manufactured by SWOT LASERS is a surgical device at the cutting edge of technology, designed for a wide variety of soft tissue procedures. The Dawn Diode Laser System utilizes a solid state diode as laser energy source. The energy is delivered to the operating area by means of a delivery system consisting of a flexible fiber connecting the laser source and the handpiece. The device is activated by means of footswitch.

This laser instrument consists of fiber connecting diode laser system, power supply system and microcomputer control system.

The Dawn Diode Laser System employs the diodes with wavelengths of 450nm, 635nm, 810nm, 980nm and 1064nm, and the device emits laser output energy in blue (450nm), red (635nm), orange (980nm) spectra respectively.

5.5 Intended Use/Indications for Use

450 nm, 635 nm and 980 nm Diode Laser:

- Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening:

- Indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy:

- Intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain

and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

810 nm Diode Laser in dentistry:

- Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, ophthalmology, and pulmonology
- Oral/Maxillofacial Indications; Incision, excision, vaporization, ablation and/or coagulation of soft tissue
- Gingival troughing for crown impression
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Excisional and incisional biopsies
- Fibroma removal
- Frenectomy and frenotomy
- Oral papillectomies
- Soft tissue crown lengthening
- Treatment of aphthous ulcers
- Treatment of herpetic lesions
- Periodontology;
- Laser soft tissue curettage
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Cosmetic Dentistry;
- Laser-assisted bleaching/whitening of the teeth
- Light activation for bleaching materials for teeth whitening
- Implant recovery

810 nm Diode Laser in therapy:

- Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

1064 nm Diode Laser in dentistry:

- Excisional and incisional biopsies;
- Excision and vaporization of herpes simplex I and II;
- Frenectomy and frenotomy;
- Gingivectomy;
- Gingivoplasty;
- Gingival incision and excision;
- Hemostasis;
- Implant recovery;
- Operculectomy;
- Pulpotomy and pulpotomy as an adjunct to root canal therapy;
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy;
- Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility);
- Treatment of aphthous ulcers and herpetic lesions

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 Dawn Diode Laser System and those of the Predicate Device 1

Proposed Device	Predicate Device 1	Discussion of the differences between proposed device and predicate device
Shanghai Wonderful Dawn Diode Laser System (To be decided)	**Guilin Woodpecker D-Laser Blue (K210367)**	
Product Code		
NVK, GEX, ILY	NVK, GEX, ILY	Same
Regulation Number		
21 CFR 878.4810	21 CFR 878.4810	Same
Classification		
Class II	Class II	Same
450 nm, 635 nm and 980 nm Diode Laser Indication for Use		
• Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy;	D-Laser Blue and D-Laser 16 are Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions;	Same

vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy. Whitening: • Indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth. Low Level Laser Therapy: • Intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary	papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy. Whitening: D-Laser Blue and D-Laser 16 are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth. Low Level Laser Therapy: D-Laser Blue and D-Laser 16 are intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation	

relaxation of muscles.	and/or temporary relaxation of muscles.	
Application		
Dental Laser	Dental Laser	Same
Laser Classification		
450 nm Laser: Class IV	450 nm Laser: Class IV	Same
635 nm Laser: Class II	650 nm Laser: Class II	Different but acceptable as Reference Device K071687: IQ 630-670.
980 nm Laser: Class IV	976 nm Laser: Class IV	Different but same as Reference Device K163128 : 980nm
Laser Type		
Solid state diode	Solid state diode	Same
Laser Wavelength		
450 nm (+/-20 nm) (430-470)	450 nm (+/-20 nm) (430-470)	Same
635 nm (+/-20 nm) (615-655)	650 nm (+/-20 nm) (630-670)	Different but same as Reference Device K111643 : 635nm ((+/-20 nm) or 615nm-655nm
980 nm (+/-20 nm) (960-1000)	976 nm (+/-20 nm) (956-996)	Different but same as Reference Device K163128 : 980 nm (+/-20 nm) or 960-1000 nm

Optical Power		
450 nm: 0.1 W - 4 W (Continuous Wave)	**450 nm**: 0.2 W - 3.0 W (Continuous Wave) 4 W (peak power)	Different but acceptable as Reference Device K202291 : 445nm: Up to 4W
635 nm: 50 mW - 300 mW (Continuous Wave)	**650 nm**: 25 mW - 200 mW (Continuous Wave)	Different but acceptable as Reference Device K071687: IQ 630-670: ≦ 5W
980 nm: 0.1 W - 8 W (Continuous Wave)	**976 nm**: 0.2 W - 4 W (Continuous Wave) 7 W (peak power)	Different but acceptable as Reference Device K202291 : 980nm: Up to 12W
Emission Modalities		
• Continuous Wave • Chopped (up to 20 kHz)	• Continuous Wave • Chopped (1 Hz - 20 kHz)	Different but acceptable as Reference Device K163128: Up to 20 kHz (20,000 Hz).
Pulse Duration		
Chopped Mode: 10 µsec - 9.9 sec.	Chopped Mode: 5 µsec To 0.9 sec.	Different but acceptable as Reference Device K163128 : 0.01-100ms (10 μ sec-100ms) and Reference Device K202991: 0.1ms-60s.
Alming Beam		

635±20 nm P_{max}＜5 mW	650±20 nm P_{max}＜5 mW	Different but acceptable as Reference Device K222701 : Red 635-650 nm (<5 mW).
Optical Fiber Surgical Tips		
Fiber Diameter: 300 µm, 400 µm	Fiber Diameter: 200 µm, 300 µm, 400 µm,	The fiber diameters of the subject device are two of those of the predicate device, so the difference can be acceptable.
• 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 non-sterile	Same
Laser Handpiece		
• 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.	Same
Laser Therapy Light Guides		
N/A	N/A	Same
Activation Method		
• Handpiece finger switch • Wireless foot switch	• Handpiece finger switch • Wireless foot switch	Same

Laser Control Unit Dimensions		
200 mm x 200 mm x 180 mm	190 mm x 180 mm x 200 mm	Due to different design scheme, the difference does not raise any new issue of substantial equivalence.
Laser Control Unit User Interface		
Color touch screen graphical user interface	Color touch screen graphical user interface	Same

Table 2 Comparison Between the Indications for Use and Technological Characteristics of Dawn Diode Laser System and those of the Predicate Device 2

Proposed Device	Predicate Device 2	Discussion of the differences between proposed device and predicate device
Shanghai Wonderful Dawn Diode Laser System (To be decided)	**Fotona d.o.o Fotona XPulse Laser System Family (XPulse 1064 nm, XPulse 810 nm, XPulse 980 nm) (K221712)**	
Product Code		
NVK, GEX, ILY	GEX	Same
Regulation Number		
21 CFR 878.4810	21 CFR 878.4810	Same
Classification		
Class II	Class II	Same
810 nm Diode Laser Indication for Use		

810 nm Diode Laser in dentistry: · Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, ophthalmology, and pulmonology · Oral/Maxillofacial Indications; Incision, excision, vaporization, ablation and/or coagulation of soft tissue · Gingival troughing for crown impression · Gingivectomy · Gingivoplasty · Gingival incision and excision · Hemostasis and coagulation · Excisional and incisional biopsies · Fibroma removal · Frenectomy and frenotomy · Oral papillectomies · Soft tissue crown lengthening · Treatment of aphthous ulcers · Treatment of herpetic lesions · Periodontology; · Laser soft tissue curettage · Laser soft tissue curettage · Laser removal of diseased, infected, inflamed and necrosed soft	810 nm Diode Laser in dentistry: · Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, ophthalmology, and pulmonology · Oral/Maxillofacial Indications; Incision, excision, vaporization, ablation and/or coagulation of soft tissue · Gingival troughing for crown impression · Gingivectomy · Gingivoplasty · Gingival incision and excision · Hemostasis and coagulation · Excisional and incisional biopsies · Fibroma removal · Frenectomy and frenotomy · Oral papillectomies · Soft tissue crown lengthening · Treatment of aphthous ulcers · Treatment of herpetic lesions · Periodontology; · Laser soft tissue curettage · Laser soft tissue curettage · Laser removal of diseased, infected, inflamed and necrosed soft	Same

tissue within the periodontal pocket · Cosmetic Dentistry; · Laser-assisted bleaching/whitening of the teeth · Light activation for bleaching materials for teeth whitening · Implant recovery 810 nm Diode Laser in therapy: · Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.	tissue within the periodontal pocket · Cosmetic Dentistry; · Laser-assisted bleaching/whitening of the teeth · Light activation for bleaching materials for teeth whitening · Implant recovery 810 nm Diode Laser in therapy: · Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.	
980 nm Diode Laser Indication for Use		
• Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of	980 nm Diode Laser in dentistry: • Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, pulmonology and thoracic surgery • Gingival troughing • Crown lengthening • Gingivoplasty • Coagulation	Similar, and same as the Predicate Device K210367: D-Laser Blue

aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy. Whitening: • Indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth. Low Level Laser Therapy: • Intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	• Implant uncovery • Implant recovery • Soft tissue curettage • Sulcular debridement • Biopsy • Frenectomy • Hemostasis of donor site • Operculectomy • Exposure of unerupted teeth • Pulpotomy • Treatment of aphthous ulcers • Excision of lesions • Light activation of bleaching materials for teeth whitening	
1064 nm Diode Laser Indication for Use		

1064 nm Diode Laser in dentistry: • Excisional and incisional biopsies; • Excision and vaporization of herpes simplex I and II; • Frenectomy and frenotomy; • Gingivectomy; • Gingivoplasty; • Gingival incision and excision; • Hemostasis; • Implant recovery; • Operculectomy; • Pulpotomy and pulpotomy as an adjunct to root canal therapy; • Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy; • Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility); • Treatment of aphthous ulcers and herpetic lesions	1064 nm Diode Laser in dentistry: • Excisional and incisional biopsies; • Excision and vaporization of herpes simplex I and II; • Frenectomy and frenotomy; • Gingivectomy; • Gingivoplasty; • Gingival incision and excision; • Hemostasis; • Implant recovery; • Operculectomy; • Pulpotomy and pulpotomy as an adjunct to root canal therapy; • Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy; • Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility); • Treatment of aphthous ulcers and herpetic lesions 1064 nm Diode Laser in dermatology and other surgical areas: • General surgery indications: surgical incision, excision, vaporization and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartillage, meniscus, mucous membrane, lymph vessels and nodes, organs	Same

	and glands, fibroma removal; • Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy, Periungual and subungual warts, Plantar warts, Radical nail excision, Neuromas. • Temporary increase of clear nail in patients with onychomycosis (e.g. dermatophytes Trichophyton rubrum and T mentagrophytes and/or yeasts Candida albicans, etc.); 1064 nm Diode Laser in therapy • Temporary relief of muscle and joint pain and stiffness, arthritis pain or muscle spasm, temporary increase in local blood circulation and/or promoting relaxation of muscle.	
Engergy source		
Solid State Diode	Solid State Diode	Same
Wavelength		
810 nm	810 nm	Same
980 nm	980 nm	Same
1064 nm	1064 nm	Same
Aiming beam		
810 nm: Laser diode 635 nm (red); < 5 mW	**810 nm**: Laser diode 532 nm (green); < 1 mW	Different but acceptable as Reference Device K222701 : Red 635-650 nm (<5 mW).

980 nm: Laser diode 635 nm (red); < 5 mW	**980 nm**: Laser diode 532 nm (green); < 1 mW	Different but acceptable as Reference Device K222701 : Red 635-650 nm (<5 mW).
1064 nm: Laser diode 635 nm (red); < 5 mW	**1064 nm**: Laser diode 532 nm (green); < 1 mW	Different but acceptable as Reference Device K222701 : Red 635-650 nm (<5 mW).
Power		
810 nm: 0.1 W - 8 W (optional)	**810 nm**: Up to 8 W	Same
980 nm: 0.1 W - 8 W	**980 nm**: Up to 12 W	Same
1064 nm: 0.1 W - 10 W	**1064 nm**: Up to 10 W	Same
Pulse width		
810 nm: 10 µs - 9.9 s/CW	**810 nm**: 0.1 ms - 45 s/CW	Different but acceptable as Reference Device K163128 : 0.01-100ms (10 μ sec-100ms) and Reference Device K202991: 0.1ms-60s.
980 nm: 10 µs - 9.9 s/CW	**980 nm**: 0.1 ms - 45 s/CW	Different but acceptable as Reference Device K163128 : 0.01-100ms (10 μ sec-100ms) and Reference Device K202991: 0.1ms-

		60s.
1064 nm: 10 µs - 9.9 s/CW	**1064 nm**: 0.1 ms - 45 s/CW	Different but acceptable as Reference Device K163128 : 0.01-100ms (10 μ sec-100ms) and Reference Device K202991: 0.1ms-60s.
Repetition rate		
810 nm: Up to 20 kHz/CW	**810 nm**: Up to 200 Hz/CW	Different but acceptable as Reference Device K163128: Up to 20 kHz (20,000 Hz).
980 nm: Up to 20 kHz/CW	**980 nm**: Up to 200 Hz/CW	Different but acceptable as Reference Device K163128: Up to 20 kHz (20,000 Hz).
1064 nm: Up to 20 kHz/CW	**1064 nm**: Up to 200 Hz/CW	Different but acceptable as Reference Device K163128: Up to 20 kHz (20,000 Hz).
Delivery system		
810 nm: Contact and non-contact handpieces connected to the system via fiber delivery	**810 nm**: Contact and non-contact handpieces connected to the system via fiber delivery	Same
980 nm: Contact and non-contact handpieces connected to the system via fiber delivery	**980 nm**: Contact and non-contact handpieces connected to the system via fiber delivery	Same

1064 nm: Contact and non-contact handpieces connected to the system via fiber delivery	**1064 nm**: Contact and non-contact handpieces connected to the system via fiber delivery	Same
User interface		
810 nm: Touch screen control	**810 nm**: Touch screen control	Same
980 nm: Touch screen control	**980 nm**: Touch screen control	Same
1064 nm: Touch screen control	**1064 nm**: Touch screen control	Same

From above two tables, the proposed device Dawn Diode Laser System and the predicate devices D-Laser Blue and Fotona XPulse Laser System Family (XPulse 1064 nm, XPulse 810 nm, XPulse 980 nm) have the same indications for use respectively. Although there are subtle technological characteristic differences between the proposed device and its 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 Dawn Diode Laser System, the following tests were performed. It shows that the testing results do support substantial equivalence.

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60825-1 Edition 2.0 2007-03
Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

IEC 60601-2-22 Edition 3.1 2012-10
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
Medical devices - Part 1: Application of usability engineering to medical devices

EC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
Medical device software - Software life cycle processes

ISO 10993-1 Fifth edition 2018-08
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Third edition 2009-06-01
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10 Fourth edition 2021-11
Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23 First edition 2021-01
Biological evaluation of medical devices - Part 23: Tests for irritation

ISO 14971 Third Edition 2019-12
Medical devices - Application of risk management to medical devices

IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-1-9
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design

ISO 17664-1 First edition 2021-07
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

Summarize studies conducted utilizing Dawn comparing the cutting efficiency of the predicate devices.

5.8 Brief discussion of clinical tests

No human clinical data is needed for Dawn Diode Laser System.

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, Shanghai Wonderful Opto-Electrics Tech Co., Ltd. concludes that:

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