March 4, 2024

Gigaalaser Company Ltd.
Xinxing Nie
Regulations Control Manager
304, 306, 3F No.3 plant, Building B10
Wuhan Hi-Tech Medical Device Industrial Park
Wuhan, Hubei 430206
CHINA

Re: K230047
Trade/Device Name: Medical Diode Laser Systems
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: NVL, GEX, ILY, EEG
Dated: February 2, 2024
Received: February 2, 2024

Dear Xinxing Nie:

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

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)*
K230047

Device Name
Medical Diode Laser Systems

Indications for Use *(Describe)*
Medical Diode Laser Systems 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;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: Medical Diode Laser Systems are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.
Low Level Laser Therapy: Medical Diode Laser Systems are intended 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.

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."

Section 5 510(k) summary

K230047

I Submitter

Device submitter: Gigaalaser Company Ltd.
Add.: 304, 306, 3F No.3 plant, Building B10, Wuhan Hi-Tech Medical Device Industrial Park, #818 Gaoxin Avenue, East Lake Development Zone, Wuhan,China (Free Trade Zone Wuhan Area)

Contact person: Xinxing Nie
Title: Regulations Control Manager
Phone: +86-27-18086025718
Fax: +86-27-6784 8873
Email: fdagigaalaser@sohu.com

II Device

Trade Name of Device:	Medical Diode Laser Systems
Common name:	Dental diode laser
Classification name:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Classification:	Class II, 21 CFR 878.4810
Primary Product Code:	NVK
Secondary Product Codes:	GEX, ILY
Review Panel:	General & Plastic Surgery
Submission number:	Unknown

III Predicate Device and Reference Device

Primary Predicate Device

Trade name:	D-Laser Blue, D-Laser 16
Common name:	Dental Diode Lasers
Regulation number:	21 CFR 878.4810
Classification Name:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory class:	Class II
Product code:	NVK, GEX, ILY
Submitter:	Guilin Woodpecker Medical Instrument Co., Ltd.
510(k) number:	K210367

Reference Predicate Device

Trade name:	Gemini 810+980 Diode Laser

Common name:	Powered laser surgical instrument, Infrared lamp
Regulation number:	21 CFR 878.4810
Classification Name:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology; and infrared lamp
Regulatory class:	Class II
Product code:	GEX, ILY
Submitter:	Azena Medical, LLC
510(k) number:	K192617

IV Device description

The Medical Diode Laser System is a compact, air-cooled unit. It is a complete self-contained instrument, which includes a high efficiency power supply, a microprocessor controlled, adjustable light output with automatic power stabilization, (fan cooled), as well as a switch panel and LCD screen display panel designed to be user friendly. The system includes high power lasers, safety features and an SMA fiber output connector. The system includes a Lithium battery, it can work 1hour when not external power input at maximum power output in pulse or CW but intermittent mode.

The diodes are made from GaAlAs semiconductor material for high output and superior reliability. The diode lasers are enclosed in a rugged, factory-aligned, replaceable, environmentally protective module. High-capacity fans eliminate the need for water-cooling, and assure low maintenance and reliable laser operation. The diodes convert electric energy into coherent laser radiation with a wavelength of 810nm or 980nm+/-10nm (pilot beam: 650nm+/-10nm).

The product is divided into 10 models according to wavelength and output power:

Product	Model	Output power	Laser Wavelength
Medical Diode Laser Systems	DEN7A	0.1W-7W (±20%)	810nm±10nm
	DEN7B	0.1W-7W (±20%)	980nm±10nm
	DEN10B	0.1W-10W (±20%)	980nm±10nm
	CHEESEII-7A	0.1W-7W (±20%)	810nm±10nm
	CHEESEII-7B	0.1W-7W (±20%)	980nm±10nm
	CHEESEII-10B	0.1W-10W (±20%)	980nm±10nm
	GBOX-20B	1-20W (±10%)	980nm±10nm
	GBOX-15A	1-15W (±10%)	810nm±10nm
	GBOX-15B	1-15W (±10%)	980nm±10nm
	GBOX-15AB	810nm/980nm: 1-15W (±10%) 810nm+980nm: 1W-15W	810nm±10nm 980nm±10nm 810nm+980nm(±10nm)

		(±10%)	

V Indications for use

Medical Diode Laser Systems 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; 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: Medical Diode Laser Systems are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: Medical Diode Laser Systems are intended 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.

VI Comparison of technological characteristics with the predicate devices

The Medical Diode Laser System has the same intended use and principal operation, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Medical Diode Laser System and predicate devices do not alter suitability of the proposed device for its intended use.

Item	**Proposed device**	**Predicate device (K210367)**	**Reference device (K192617)**	**Discussion**
	Medical Diode Laser Systems	D-Laser Blue, D-Laser 16	Gemini 810+980 Diode Laser	
Product Code	NVK, GEX, ILY	NVK, GEX, ILY	GEX, ILY	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Classification	Class II	Class II	Class II	Identical
Indication for Use	Medical Diode Laser Systems 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	D-Laser Blue and D-Laser 16 are intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and interdental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation	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	Substantial Equivalence The reference device does not have the intended use for light activation for bleaching materials for teeth

Item	Proposed device	Predicate device (K210367)	Reference device (K192617)	Discussion
	Medical Diode Laser Systems	D-Laser Blue, D-Laser 16	Gemini 810+980 Diode Laser	
	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	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;	impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis and coagulation • Implant recovery • Incision and drainage of abscess • Leukoplakia • 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 • Treatment of aphthous ulcers. • Vestibuloplasty • Tissue retraction for impression • Lesion (tumor) removal Laser Periodontal Procedures	whitening and for laser-assisted whitening/bleaching of teeth. While the intended use of proposed device is same as the predicated device (K210367), this difference does not affect the safety and effectiveness.

Item	Proposed device	Predicate device (K210367)	Reference device (K192617)	Discussion
	Medical Diode Laser Systems	D-Laser Blue, D-Laser 16	Gemini 810+980 Diode Laser	
	incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.	treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.	• Laser soft tissue curettage. • 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 and junctional epithelium. • 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) • Reduction of bacterial level (decontamination) and inflammation	
	Whitening: Medical Diode Laser Systems are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.	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.	NA	
	Low Level Laser Therapy: Medical	Low Level Laser Therapy: D-Laser	Pain therapy:	

Item	Proposed device	Predicate device (K210367)	Reference device (K192617)	Discussion
	Medical Diode Laser Systems	D-Laser Blue, D-Laser 16	Gemini 810+980 Diode Laser	
	Diode Laser Systems are intended 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.	Blue and D-Laser 16 are intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	• Topical heating for the purpose of elevating tissue temperature for a 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.	
Application	Dental Laser	Dental Laser	Dental Laser	Identical
Laser Classification	Class IV	976 nm and 450nm: Laser: Class IV 650 nm Laser: Class II	Class IV	Substantial Equivalence
Type of Laser	Diode Laser	Diode Laser	Diode Laser	Identical
Wavelength	810 ± 10nm; 980 ± 10nm;	976 nm (+/-20 nm); 650 nm (+/-20 nm); 450 nm (+/-20 nm);	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	Substantial Equivalence According to K192617, the modification

Item	Proposed device	Predicate device (K210367)	Reference device (K192617)	Discussion
	Medical Diode Laser Systems	D-Laser Blue, D-Laser 16	Gemini 810+980 Diode Laser	
				does not adversely affect safety and effectiveness
Average Power	DEN7A/DEN7B: 0.1W-7W; DEN10B: 0.1W-10W;	D-Laser Blue 976nm: 0.2 W – 4 W (Continuous Wave) 7 W (peak power); D-Laser 16 976nm: 0.3 W – 7 W (Continuous Wave) 16 W (peak power);	0.1-2W; 20W (peak power)	Similar as the predate device.
	CHEESEII-7A/7B: 0.1W-7W; CHEESEII-10B: 0.1W-10W;	D-Laser Blue 976nm: 0.2 W – 4 W (Continuous Wave) 7 W (peak power); D-Laser 16 976nm: 0.3 W – 7 W (Continuous Wave) 16 W (peak power);	0.1-2W; 20W (peak power)	Similar as the predate device.
	GBOX-20B: 1-20W; GBOX-15A/15B: 1-15W; GBOX-15AB: 1-15W.	D-Laser Blue 976nm: 0.2 W – 4 W (Continuous Wave) 7 W (peak power); D-Laser 16 976nm:	0.1-2W; 20W (peak power)	Similar as the reference device

Item	Proposed device	Predicate device (K210367)	Reference device (K192617)	Discussion
	Medical Diode Laser Systems	D-Laser Blue, D-Laser 16	Gemini 810+980 Diode Laser	
		0.3 W – 7 W (Continuous Wave) 16 W (peak power);		
Operation Mode	Continuous Wave; Pulse	Continuous Wave; Pulse	Pulse	Identical to the predicate
Pulse width	DEN7A/ DEN7B/DEN10B: 1ms-1000ms; CHEESEII-7A/7B/10B: 25μs -10s GBOX-15A/ 15B/ 15AB/20B: 25μs -10s	5 μsec. To 0.9 sec.	Variable	Similar
Pulse repetition rate	DEN7A/ DEN7B/DEN10B: 0.5Hz-500Hz CHEESEII-7A/7B/10B: 0.05Hz-20 KHz GBOX-15A/ 15B/ 20B: 0.05Hz-20 KHz GBOX-15AB: 1Hz-20 KHz	1 Hz – 20 kHz	50Hz	Similar
Aiming Beam	650±10 nm, 5mw (max)	650±20 nm, Pmax＜5 mW	5mW laser diode, 650nm, Class 1	Substantial Equivalence
Delivery system	Fiber optic cable (200μm, 400μm, 600μm and 800μm), handpiece and fiber tips	Fiber optic cable (200μm, 300μm, 400 μm), handpiece and Single-use fiber tips	Fiber optic cable (400μm) and fiber tips	Substantial Equivalence
Operation	Color touch screen graphical user	Color touch screen graphical user	Electroluminescent glass display with	Substantial

Item	Proposed device	Predicate device (K210367)	Reference device (K192617)	Discussion
	Medical Diode Laser Systems	D-Laser Blue, D-Laser 16	Gemini 810+980 Diode Laser	
interface	interface	interface	capacitive touch interface. Capacitive touch is a hard plastic.	Equivalence
Activation Means	Foot Switch, with electronic access key	Handpiece finger switch. Wireless foot switch.	Wireless Foot Switch, with electronic access key	Substantial Equivalence

VII Summary of Non-clinical tests:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Medical Diode Laser System.

- Verify the conformity of the proposed devices with the requirements of IEC 60601-1:(Medical electrical equipment Part 1: General requirements for basic safety and essential performance).
- Verify the conformity of the proposed devices with the requirements of IEC 60601-1-2:(Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic compatibility).
- Verify the conformity of the proposed devices to IEC 60825-1 (Safety of laser products - Part 1: Equipment classification and requirements).
- Verify the performance of the proposed devices according to IEC 60601-2-22: (Medical electrical equipment Part 2: Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment).

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

VIII Clinical Testing

It is not applicable.

IX Conclusion

The Medical Diode Laser System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.