Build Correspondence | Convert to PDF

U.S. FOOD & DRUG ADMINISTRATION

May 19, 2025

Gigaalaser Company Ltd.
Xinxing Nie
Regulations Control Manager
B15-8F, Wuhan Hi-Tech Medical device park, #818 Gaoxin Road
Wuhan, Hubei
China

Re: K242755
Trade/Device Name: Medical Diode Laser Systems (VELAS II-30B, VELAS II-30A, GBOX-15AB, GBOX-20B, CHEESE II-10B)
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: PDZ, ILY
Dated: September 11, 2024
Received: September 12, 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.05.19 19:44:03 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242755

Device Name
Medical Diode Laser Systems (VELAS II-30B, VELAS II-30A, GBOX-15AB, GBOX-20B, CHEESE II-10B)

Indications for Use *(Describe)*
The Medical Diode Laser Systems, include model: VELASII-30A, GBOX-15AB, GBOX-20B, CHEESEII-10B are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.

The Medical Diode Laser Systems, model: VELASII-30B is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.

The Medical Diode Laser Systems, model: VELASII-30B is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

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.

510(k) Summary-K242755

I. SUBMITTER

Gigaalaser Company Ltd.

Add.: B15-8F, Wuhan Hi-Tech Medical device park, #818 Gaoxin Road, Wuhan 430206, China

Phone: +86 18062575326

Fax: +86-27-6784 8873

Contact Person: Xinxing Nie

Date Prepared: December 6, 2024

II. DEVICE

Name of Device:	Medical Diode Laser Systems
Model:	VELASII-30B, VELASII-30A, GBOX-20B, GBOX-15AB, CHEESEII-10B
Regulation number:	21 CFR 890.5500 21 CFR 878.4810
Regulation name:	Infrared lamp Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name:	Lamp, Infrared, Therapeutic Heating Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis
Regulatory class:	Class II
Product code:	ILY, PDZ

III. PREDICATE DEVICE

Primary Predicate Device

Trade name:	VELASII THERAPY LASER SYSTEM
Classification name:	Lamp, Infrared, Therapeutic Heating
Regulation number:	21 CFR 890.5500
Regulation name:	Infrared lamp
Regulatory class:	Class II

Product code:	ILY
Submitter:	Aspen Laser Systems, LLC
510(k) number:	K142078

Co-predicate	
Device Trade name:	Aspen Laser Systems Therapy Laser System
Classification name:	Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis
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:	PDZ, GEX
Submitter:	Aspen Laser Systems, LLC
510(k) number:	K150138

Co-predicate Device	
Trade name:	Diowave Laser System
Classification name:	Lamp, Infrared, Therapeutic Heating
Regulation number:	21 CFR 890.5500
Regulation name:	Infrared lamp
Regulatory class:	Class II
Product code:	ILY
Submitter:	TECHNOLOGICAL MEDICAL ADVANCMENTS, INC. (TMA)
510(k) number:	K121363

Co-predicate Device	
Trade name:	Medical Diode Laser Systems
Classification name:	Lamp, Infrared, Therapeutic Heating
Regulation number:	21 CFR 890.5500

Regulation name:	Infrared lamp
Regulatory class:	Class II
Product code:	ILY
Submitter:	Gigaalaser Company Ltd.
510(k) number:	K230047

IV. DEVICE DESCRIPTION

The “Medical Diode Laser Systems”, include model: VELAS Ⅱ-30B, VELAS Ⅱ-30A, GBOX-15AB, GBOX-20B, CHEESE Ⅱ-10B which consist of three main components:

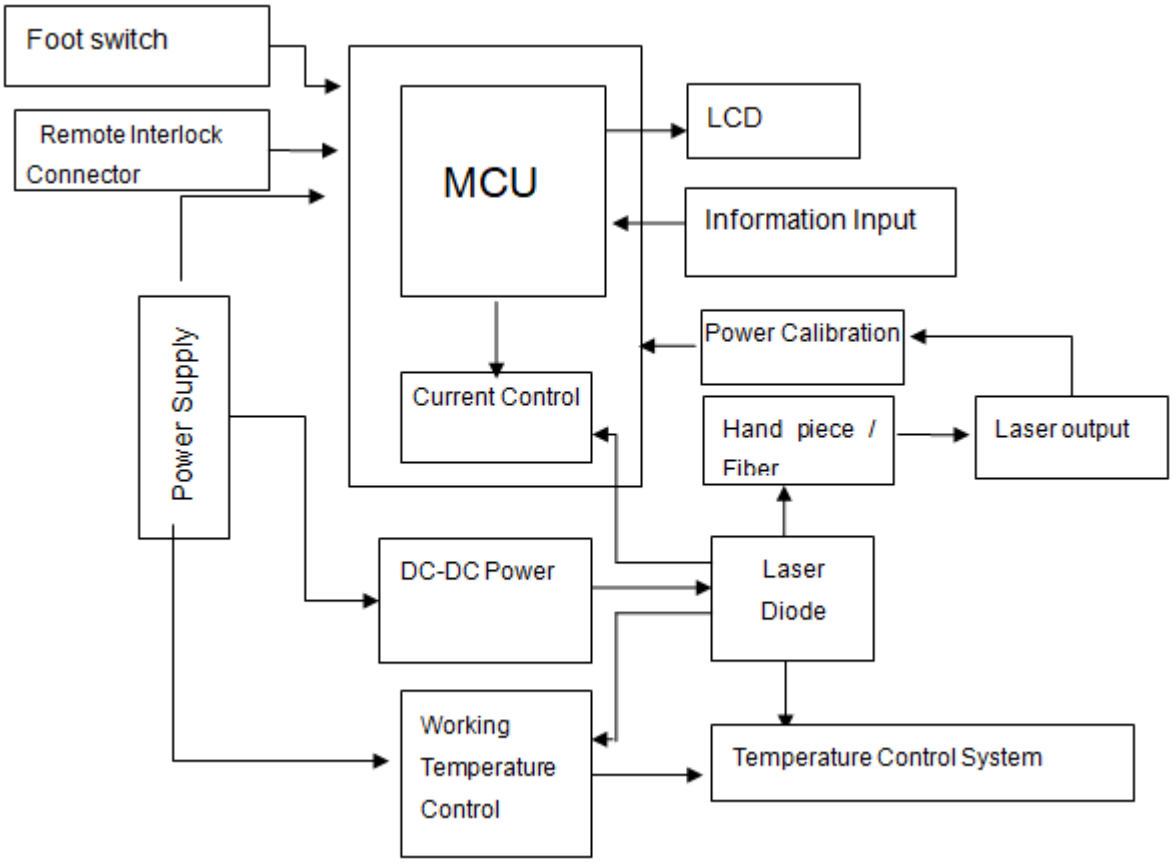
(1) Main device;

(2) Foot switch;

(3) Accessories.

Diode laser is a kind of laser with semiconductor as working material. It consists of working material, cavity resonator and power source.

The diode laser for this unit is GaAlAs diode bar, and the wavelength is 810nm and/or 980nm+/-10nm (pilot beam: 650nm+/-10nm). It features impact structure, high efficiency and long lifetime. Generally, the beam shall be emitted as the big beam divergence of the laser from the diode. With the unique fiber-coupling technology, the laser beam can be coupled efficiently into the fiber.



MCU (Micro Controller Unit) is the control center of system. MCU controls the drive board and temperature system by changing operating current. The operating power supply is the power source of the whole system. It supplies power for MCU, diode laser module by DC-DC conversion module and temp system by temp-control circuit. MCU controls the drive current of diode laser module by adjusting the DC-DC module and current-control circuit. The MCU has three external input sources: footswitch, remote interlock connector and information input from the touch units, it has one external output unit: display terminal. The diode laser module provides laser power output by fiber with optical fiber coupling system.

V. INDICATIONS FOR USE

(1) The Medical Diode Laser Systems, include model: VELAS Ⅱ-30A, GBOX-15AB, GBOX-20B, CHEESE Ⅱ-10B are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.

(2) The Medical Diode Laser Systems, model: VELAS Ⅱ-30B are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.

The Medical Diode Laser Systems , model: VELAS Ⅱ-30B are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1 Substantial equivalence discussion (Medical diode laser systems, Model: VELASII-30B for physical therapy mode)

Item	**Proposed device** (Physical therapy mode)	**Primary predicate device**	**Discussion**
510k Number	**K242755**	K142078	/
Proprietary Name	Medical diode laser systems	VELASII THERAPY LASER SYSTEM	/
Model	VELASII-30B	VELASII	/
Product Code	ILY	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	Identical
Classification	Class II	Class II	Identical
Indication for Use	The Medical Diode Laser Systems is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	The VelasII Therapy Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating, tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	Identical
Laser type	diode laser	diode laser	Identical

Wavelength	980nm±10nm	980nm±10nm	Identical
Output power	1-30W(±20%)	Up to 30 Watt max (VELASII-30) Up to 60 Watt max (VELASII-60)	Different Comment 1
Energy Density(ED /) (Fluence)	0.05~3.1 J/cm^2 (Per second)	VELASII-30: 0.05~3.1 J/cm^2 (Per second) VELASII-60: 0.05~6.2 J/cm^2 (Per second)	Different Comment 2
Power Density	0.05~3.1 W/cm^2	VELASII-30: 0.05~3.1 W/cm^2 VELASII-60: 0.05~6.2 J/cm^2 (Per second)	Different Comment 3
Spot Diameter	3.5~5 cm	3.5~5 cm	Identical
Working distance	3~5 cm	3~5 cm	Identical
Treatment angle	Perpendicular to the treatment area	Perpendicular to the treatment area	Identical
Applied part moving speed	3~5 cm/s	3~5 cm/s	Identical
Beam divergence	Working beam: 25° Aiming beam: 25°	Working beam: 25° Aiming beam: 25°	Identical
Operation mode	CW, single pulse, repeat pulse	CW	Different Comment 4
Pulse width	10ms-1s	/	Different Comment 5
Pulse repetition rate	0.5Hz-50Hz	/	Different Comment 6
Treatment	Non-contact	Non-contact	Identical

methods			
Treatment mode	Physical therapy mode	Physical therapy mode	Identical
Applied part	Handpiece	Handpiece	Identical
Transmission system	fibers of 600μm with SMA905 connector	fibers of 400μm with SMA905 connector	Different Comment 7
Aiming beam	Diode laser of 650nm, power ≤2mW, adjustable brightness.	Diode laser of 650nm power max.＜5mW, adjustable brightness.	Different Comment 8
Operation interface	Color LCD touch screen	Color LCD touch screen	Identical
Power supply	100-240VAC, 50-60Hz, 350VA	100-240VAC, 50/60Hz, 350VA	Identical
Laser Class	4	4	Identical
Safety classification	ClassI Type B	ClassI Type B	Identical
Cooling	Air	Air	Identical
Dimensions	400(W)*385(L)*200(H)mm	400(W)*385(L)*200(H)mm	Identical
Weight	12.9kg	12.9kg	Identical
Waterproof level	IPX1	IPX1	Identical
Footswitch Waterproof level	IPX8	IPX8	Identical
Operating	Temperature is 5℃~40℃, relative humidity is less	Temperature is 5℃~40℃, relative humidity	Identical

Environment	than 80%, and atmospheric pressure is 86kPa~106kPa.	is less than 80%, and atmospheric pressure is 86kPa~106kPa.	
Storage Environment	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 50kPa~106kPa.	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 50kPa~106kPa.	Identical

Discussion:

Clinical: Indication for Use claimed by proposed device is the same with the predicate device K142078.

Technology: The proposed device uses same 980nm diode lasers technology as that used by the predicate. The output parameters of the proposed device are similar to the output parameters of the predicates. The main differences are Output power, Energy Density (ED) / (Fluence), Power density, Operation mode, Pulse width, Pulse repetition rate, Transmission system and Aiming beam.

Comment 1 Output power:

The output power of the proposed device: 1-30W, which is different to the predicate device: VELASII-60 (Up to 60 Watt max), but identical to the predicate device: VELASII-30 (Up to 30 Watt max). To sum up, the output power of the proposed device is within the scope of what predicate device claims.

Comment 2 Energy Density (ED) / (Fluence):

The energy density (ED) / (fluence) of the proposed device: 0.05~3.1 J/cm^2 (Per second), which is different to the predicate device: VELASII-60 (0.05~6.2 J/cm^2), but identical to the predicate device VELASII-30 (0.05~3.1 J/cm^2). To sum up, the Energy Density (ED) / (Fluence) of the proposed device is within the scope of what predicate device claims.

Comment 3 Power Density:

The power density of the proposed device: 0.05~3.1 W/cm^2 (Per second), which is different to the predicate device: VELAS Ⅱ-60 (0.05~6.2 W/cm^2), but identical to the predicate device VELAS Ⅱ-30 (0.05~3.1 W/cm^2). To sum up, the power density of the proposed device is within the scope of what predicate device claims.

Comment 4 Operation mode:

The operation mode of the proposed device (CW, single pulse, repeat pulse) is different to the predicate device (CW). Compared with the predicate device, the proposed device has pulse mode additionally. Compared with the CW mode, the energy density in this mode is lower than that in the CW mode, and it will be safer to use.

Comment 5 Pulse width:

The pulse width of the proposed device (10ms-1s), which is different to the predicate device (CW mode only, there is no pulse width in CW mode), but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 6 Pulse repetition rate:

The repetition rate of the subject device (0.5Hz-50Hz), which is different to the predicate device (CW mode only, there is pulse repetition rate in CW mode), but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 7 Transmission system

The transmission system of the subject device (fibers of 600μm with SMA905 connector), which is different to the predicate device (fibers of 400μm with SMA905 connector).

The application parts of subject device and predicate device are handpiece, and the spot diameter is the same. Moreover, the transmission system only transmits laser energy. Although the optical fiber core diameter of optical fiber transmission system is different, it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 8 Aiming beam:

The aiming beam of the proposed device (Diode laser of 650nm, power ≤2mW, adjustable brightness) is different to the predicate device (Diode laser of 650nm power max.＜5mW, adjustable brightness). The aiming beam power of the proposed device is within the scope of what predicate device claims.

Conclusion:

The proposed device uses same diode lasers technology as that used by the predicate. The output parameters of the proposed device are similar to the output parameters of the predicate. The differences only exist in such contents: Output power, Energy Density (ED) / (Fluence), Power density, Operation mode, Pulse width, Pulse repetition rate, Transmission system and Aiming beam, that all can be controlled in range of application. These differences are slight in the output parameters do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

The indications for use of the subject device claimed by proposed device have been covered by predicate device and also do not raise new types of questions regarding safety and effectiveness.

So the proposed device is Substantially Equivalent (SE) to existing legally marketed predicate device.

Table 2 Substantial equivalence discussion (Medical diode laser systems, Model: VELASII-30B for general mode)

Item	**Proposed device** (General mode)	**Co-predicate device** (The temporary increase of clear nail in patients with onychomycosis)	**Discussion**
510k Number	**K242755**	K150138	/
Proprietary Name	Medical diode laser systems	Aspen Laser Systems Therapy Laser System	/
Model	VELASII-30B	VELASII	/
Product Code	PDZ	PDZ, GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Identical
Classification	Class II	Class II	Identical
Indication for Use	The Medical Diode Laser Systems is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including. *Matrixectomy, periungual and subungual warts, neuromas, and plantar warts. The VelasII is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g. dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts	Substantial Equivalence Indication for Use claimed by proposed device has been covered by predicate device.

		Candida albicans, etc.).	
Laser type	diode laser	diode laser	Identical
Wavelength	980nm±10nm	980nm±10nm	Identical
Output power	1-10W(±20%)	30 Watts in Nail Mode	Different Comment 1
Energy Density(ED) / (Fluence)	1.7~39.8 J/cm^2 (Per second)	14.1~141.5 J/cm^2 (Per second)	Different Comment 2
Power Density	1.7~39.8 W/cm^2	14.1~141.5 W/cm^2	Different Comment 3
Spot Diameter	4~5 mm	3 mm	Different Comment 4
Working distance	3~4 mm	3~4 mm	Identical
Treatment angle	Perpendicular to the treatment area	Perpendicular to the treatment area	Identical
Applied part moving speed	1~2 cm/s	1~2 cm/s	Identical
Beam divergence	Working beam: 25° Aiming beam: 25°	Working beam: 25° Aiming beam: 25°	Identical
Operation mode	Pulse	CW	Different Comment 5
Pulse width	Ton: 10ms Toff: 10ms, 20ms	/	Different Comment 6
Pulse repetition rate	33.3Hz / 50Hz	/	Different

			Comment 7
Treatment methods	Non-contact	Non-contact	Identical
Treatment mode	General mode	General mode	Identical
Applied part	600μm fiber	400μm, 600μm fiber	Different Comment 8
Transmission system	fibers of 600μm with SMA905 connector.	fibers of 400μm, 600μm with SMA905 connector.	Different Comment 9
Aiming beam	Diode laser of 650nm, power ≤2mW, adjustable brightness.	Diode laser of 650nm power max. ＜5mW, adjustable brightness.	Different Comment 10
Operation interface	Color LCD touch screen	Color LCD touch screen	Identical
Power supply	100-240VAC, 50-60Hz, 350VA	100-240VAC, 50/60Hz, 350VA	Identical
Laser Class	4	4	Identical
Safety classification	Class I Type B	Class I Type B	Identical
Cooling	Air	Air	Identical
Dimensions	400(W)*385(L)*200(H)mm	400(W)*385(L)*200(H)mm	Identical
Weight	12.9kg	12.9kg	Identical
Waterproof level	IPX1	IPX1	Identical
Footswitch Waterproof level	IPX8	IPX8	Identical

Operating Environment	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 86kPa~106kPa.	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 86kPa~106kPa.	Identical
Storage Environment	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 50kPa~106kPa.	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 50kPa~106kPa.	Identical

Discussion:

Clinical: Indication for Use claimed by proposed device has been covered by predicate device K150138 which depends on product performance, and this difference does not affect safety and effectiveness.

Technology: The proposed device uses same 980nm diode lasers technology as that used by the predicate. The output parameters of the proposed device are similar to the output parameters of the predicate. The main differences are Output power, Energy Density (ED) / (Fluence), Power density, Spot Diameter, Operation mode, Pulse width, Pulse repetition rate, Applied part, Transmission system and Aiming beam.

Comment 1 Output power:

The output power of the proposed device (1-10W), which is different to the predicate device (30 Watts in Nail Mode), but within the scope of what predicate device claims.

Comment 2 Energy Density (ED) / (Fluence):

The energy density (ED) / (fluence) of the proposed device: 1.7~39.8 J/cm^2 (Per second), which is different to the predicate device: 30 Watts in Nail Mode (14.1~141.5 J/cm^2), but within the scope of what predicate device claims.

Comment 3 Power Density:

The power density of the proposed device: 1.7~39.8 W/cm^2 (Per second), which is different to the predicate device: 30 Watts in Nail Mode (14.1~141.5 W/cm^2), but within the scope of what predicate device claims.

Comment 4 Spot Diameter

The spot diameter of the proposed device (4~5 mm) is different to the predicate device (3 mm). Although the spot of the proposed device is slightly larger (1~2mm) than that of the predicate device, the energy density is within the scope of the predicate device, it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 5 Operation mode:

The operation mode of the proposed device (Pulse) is different to the predicate device (CW). Compared with the predicate device, the proposed device has one more pulse mode. Compared with the CW mode, the energy density in this mode is lower than that in the CW mode, and it will be safer to use.

Comment 6 Pulse width:

The pulse width of the proposed device (Ton: 10ms Toff: 10ms, 20ms), which is different to the predicate device (CW mode only, there is no pulse width in CW mode), but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 7 Pulse repetition rate:

The repetition rate of the subject device (33.3Hz / 50Hz), which is different to the predicate device (CW mode only, there is pulse repetition rate in CW mode), but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 8 Applied part

The **Applied part** of the subject device (600μm fiber), which is different to the predicate device (400μm, 600μm fiber), but within the scope of what predicate device claims and it meets the clinical needs.

Comment 9 Transmission system

The transmission system of the subject device (fibers of 600μm with SMA905 connector), which is different to the predicate device (fibers of 400μm, 600μm with SMA905 connector), but within the scope of what predicate device claims and it meets the clinical needs.

Comment 10 Aiming beam:

The aiming beam of the proposed device (Diode laser of 650nm, power ≤2mW, adjustable brightness) is different to the predicate device (Diode laser of 650nm power max.＜5mW, adjustable brightness). The aiming beam power of the proposed device is within the scope of what predicate device claims.

Conclusion:

The proposed device uses same diode lasers technology as that used by the predicates. The output parameters of the proposed device are similar to the output parameters of the predicates. The differences only exist in such contents: Output power, Energy Density (ED) / (Fluence), Power density, Spot Diameter, Operation mode, Pulse width, Pulse repetition rate, Applied part, Transmission system and Aiming beam, that all can be controlled in range of application. These differences are slight in the output parameters do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

The indications for use of the subject device claimed by proposed device have been covered by predicate device and also do not raise new types of questions regarding safety and effectiveness.

So, the proposed device is Substantially Equivalent (SE) to existing legally marketed predicate device.

Table3 Substantial equivalence discussion (Medical diode laser systems, Model: VELASII-30A)

Item	Proposed device	Co-predicate device	Discussion
510k Number	/	K121363	/
Proprietary Name	Medical diode laser systems	Diowave Laser System	/
Model	VELASII-30A	Diowave 30W	/
Product Code	ILY	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	Identical
Classification	Class II	Class II	Identical
Indication for Use	The Medical Diode Laser Systems is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	The Diowave Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating, tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	Identical
Laser type	diode laser	diode laser	Identical
Wavelength	810nm±10nm	810nm±10nm, 980nm±10nm	Different Comment 1

Output power	1-30W(±20%)	1-30W(±20%)	Identical
Energy Density(ED /) (Fluence)	0.05~3.1 J/cm^2 (Per second)	0.05~3.1 J/cm^2 (Per second)	Identical
Power Density	0.05~3.1 W/cm^2	0.05~3.1 W/cm^2	Identical
Spot Diameter	3.5~5 cm	3.5~5 cm	Identical
Working distance	3~5 cm	3~5 cm	Identical
Treatment angle	Perpendicular to the treatment area	Perpendicular to the treatment area	Identical
Applied part moving speed	3~5 cm/s	3~5 cm/s	Identical
Beam divergence	Working beam: 25° Aiming beam: 25°	Working beam: 25° Aiming beam: 25°	Identical
Operation mode	CW, single pulse, repeat pulse	CW, Single Pulse, Repetition Pulse	Identical
Pulse width	10ms-1s	10μs-1s	Different Comment 2
Pulse repetition rate	1Hz-50Hz	0.5Hz-10KHz	Different Comment 3

Treatment methods	Non-contact	Non-contact	Identical
Applied part	Handpiece	Handpiece	Identical
Transmission system	fibers of 600μm with SMA905 connector	fibers of 400μm, 600μm and 1000μm with SMA905 connector	Different Comment 4
Aiming beam	Diode laser of 650nm, power ≤2mW, adjustable brightness.	Diode laser of 650nm power max.＜5mW, adjustable brightness.	Different Comment 5
Operation interface	Color LCD touch screen	Color LCD touch screen	Identical
Power supply	100-240VAC, 50-60Hz, 350VA	100-240VAC, 50/60Hz, 350VA	Identical
Laser Class	4	4	Identical
Safety classification	Class I Type B	Class I Type B	Identical
Cooling	Air	Air	Identical
Dimensions	400(W)*385(L)*200(H)mm	400(W)*385(L)*200(H)mm	Identical
Weight	12.9kg	12.9kg	Identical
Waterproof level	IPX1	IPX1	Identical
Footswitch	IPX8	IPX8	Identical

Waterproof level			
Operating Environment	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 86kPa~106kPa.	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 86kPa~106kPa.	Identical
Storage Environment	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 50kPa~106kPa.	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 50kPa~106kPa.	Identical

Discussion:

Clinical: Indication for Use claimed by proposed device has been covered by predicate device (K142078) which depends on product performance, and this difference does not affect safety and effectiveness.

Technology: The proposed device uses same 810nm diode lasers technology as that used by the predicate. The output parameters of the proposed device are similar to the output parameters of the predicate. The main differences are Wavelength, Pulse width, Pulse repetition rate Transmission system and Aiming beam.

Comment 1 Wavelength:

The wavelength of the proposed device: 810nm±10nm, which is different to the predicate device Diowave 30W (810nm±10nm, 980nm±10nm), but within the scope of what predicate device claims.

Comment 2 Pulse width:

The pulse width of the proposed device (10ms-1s), which is different to the predicate device (10μs-1s), is within the scope of what predicate device claims.

Comment 3 Pulse Repetition rate:

Repetition rate of the subject device (1Hz-50Hz), which is different to other predicate device (0.5Hz-10KHz), but within the scope of what predicate device claims.

Comment 4 Transmission system

The transmission system of the subject device (fibers of 600μm with SMA905 connector), which is different to the predicate device (fibers of 400μm, 600μm and 1000μm with SMA905 connector), but within the scope of what predicate device claims and it meets the clinical needs.

Comment 5 Aiming beam:

The aiming beam of the proposed device (Diode laser of 650nm, power ≤2mW, adjustable brightness) is different to the predicate device (Diode laser of 650nm power max.＜5mW, adjustable brightness). The aiming beam power of the proposed device is within the scope of what predicate device claims.

Conclusion:

The proposed device uses same diode lasers technology as that used by the predicate. The output parameters of the proposed device are similar to the output parameters of the predicate. The differences only exist in such contents: Wavelength, Pulse width, Pulse repetition rate Transmission system and Aiming beam that all can be controlled in range of application. These differences are slight in the output parameters do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

The indications for use of the subject device claimed by proposed device have been covered by predicate device and also do not raise new types of questions regarding safety and effectiveness.

So, the proposed device is Substantially Equivalent (SE) to existing legally marketed predicate device.

Table4 Substantial equivalence discussion (Medical diode laser systems, Model: GBOX-15AB)

Item	Proposed device	Co-predicate device (Low Level Laser Therapy)	Discussion
510k Number	/	K230047	/
Proprietary Name	Medical diode laser systems	Medical diode laser systems	/
Model	GBOX-15AB	GBOX-15AB	/
Product Code	ILY	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	Identical
Classification	Class II	Class II	Identical
Indication for Use	The Medical Diode Laser Systems is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	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.	Identical The descriptions are different, but the contents are the same.
Laser type	diode laser	diode laser	Identical
Wavelength	810 ±10nm; 980 ±10nm;	810 ±10nm; 980 ±10nm;	Identical
Output power	810nm: 1W-15W(±10%), adjust step:0.1W 980nm: 1W-15W(±10%), adjust step:0.1W 810nm+980nm: 1W-15W(±10%); adjust step:0.1W	810nm: 1W-15W(±10%), adjust step:0.1W 980nm: 1W-15W(±10%), adjust step:0.1W 810nm+980nm: 1W-15W(±10%); adjust step:0.1W	Identical

Energy Density(ED) / (Fluence)	0.05~1.55 J/cm^2 (Per second)	0.05~1.55 J/cm^2 (Per second)	Identical
Power Density	0.05~1.55 W/cm^2	0.05~1.55 W/cm^2	Identical
Spot Diameter	3.5~5 cm	3.5~5 cm	Identical
Working distance	3~5 cm	3~5 cm	Identical
Treatment angle	Perpendicular to the treatment area	Perpendicular to the treatment area	Identical
Applied part moving speed	3~5 cm/s	3~5 cm/s	Identical
Beam divergence	Working beam: 25° Aiming beam: 25°	Working beam: 25° Aiming beam: 25°	Identical
Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Identical
Pulse width	25μs-10s	25μs -10s	Identical
Pulse repetition rate	1Hz-20KHz	1Hz-20KHz	Identical
Treatment methods	Non-contact	Non-contact	Identical
Applied part	Handpiece	Handpiece	Identical
Transmission system	fibers of 600μm with SMA905 connector.	fibers of 600μm with SMA905 connector.	Identical
Aiming beam	Diode laser of 650nm, power＜5mW, adjustable brightness.	650±10nm, 5mw (max)	Identical
Operation	Color LCD touch screen	Color touch screen graphical user interface	Identical

interface			
Power supply	100-240VAC, 50-60Hz, 200VA	100-240VAC, 50-60Hz, 200VA	Identical
Laser Class	4	4	Identical
Safety classification	Class I Type B	Class I Type B	Identical
Cooling	Air	Air	Identical
Dimensions	256(W)*223L)*312(H)mm	256(W)*223L)*312(H)mm	Identical
Weight	4kg	4kg	Identical
Waterproof level	IPX1	IPX1	Identical
Footswitch Waterproof level	IPX8	IPX8	Identical
Operating Environment	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 860hPa~1060hPa.	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 860hPa~1060hPa.	Identical
Storage Environment	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 500hPa~1060hPa.	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 500hPa~1060hPa.	Identical

Discussion:

Clinical: Indication for Use claimed by proposed device has been covered by predicate device (K230047 GBOX-15AB) which depends on product performance. The descriptions are different, but the contents are the same. And this difference does not affect safety and effectiveness.

Technology: The proposed device uses same 810nm/980nm/810nm+980nm diode lasers technology as that used by the predicates. The output parameters of the proposed device are same to the output parameters of the predicates.

Conclusion: The proposed device uses same diode lasers technology as that used by the predicate. The output parameters of the proposed device are same to the output parameters of the predicates

The indications for use of the subject device claimed by proposed device have been covered by predicate device and also do not raise new types of questions regarding safety and effectiveness.

So the proposed device is Substantially Equivalent (SE) to existing legally marketed predicate device.

Table5 Substantial equivalence discussion (Medical diode laser systems, Model: GBOX-20B)

Item	Proposed device	Co-predicate device (Low Level Laser Therapy)	Discussion
510k Number	/	K230047	/
Proprietary Name	Medical diode laser systems	Medical diode laser systems	/
Model	GBOX-20B	GBOX-20B	/
Product Code	ILY	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	Identical
Classification	Class II	Class II	Identical
Indication for Use	The Medical Diode Laser Systems is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	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.	Identical The descriptions are different, but the contents are the same.
Laser type	diode laser	diode laser	Identical
Wavelength	980nm±10nm	980nm±10nm	Identical
Output power	1-20W(±10%)	1-20W (±10%)	Identical

Energy Density(ED) / (Fluence)	0.05~2.1 J/cm^2 (Per second)	0.05~2.1 J/cm^2 (Per second)	Identical
Power Density	0.05~2.1 W/cm^2	0.05~2.1 W/cm^2	Identical
Spot Diameter	3.5~5 cm	3.5~5 cm	Identical
Working distance	3~5 cm	3~5 cm	Identical
Treatment angle	Perpendicular to the treatment area	Perpendicular to the treatment area	Identical
Applied part moving speed	3~5 cm/s	3~5 cm/s	Identical
Beam divergence	Working beam: 25° Aiming beam: 25°	Working beam: 25° Aiming beam: 25°	Identical
Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Identical
Pulse width	25μs-10s	25μs -10s	Identical
Pulse repetition rate	1Hz-20KHz	1Hz-20KHz	Identical
Treatment methods	Non-contact	Non-contact	Identical
Applied part	Handpiece	Handpiece	Identical
Transmission	fibers of 600μm with SMA905 connector	fibers of 600μm with SMA905 connector	Identical

system			
Aiming beam	Diode laser of 650nm, power ＜ 5mW, adjustable brightness.	650±10nm, 5mw (max)	Identical
Operation interface	Color LCD touch screen	Color touch screen graphical user interface	Identical
Power supply	100-240VAC, 50-60Hz, 200VA	100-240VAC, 50-60Hz, 200VA	Identical
Laser Class	4	4	Identical
Safety classification	Class I Type B	Class I Type B	Identical
Cooling	Air	Air	Identical
Dimensions	256(W)*223L)*312(H)mm	256(W)*223L)*312(H)mm	Identical
Weight	4kg	4kg	Identical
Waterproof level	IPX1	IPX1	Identical
Footswitch Waterproof level	IPX8	IPX8	Identical
Operating Environment	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 860hPa~1060hPa.	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 860hPa~1060hPa.	Identical
Storage	Temperature is -20℃~55℃, relative humidity is less	Temperature is -20℃~55℃, relative humidity is less	Identical

Environment	than 80%, and atmospheric pressure is 500hPa~1060hPa.	than 80%, and atmospheric pressure is 500hPa~1060hPa.	

Discussion:

Clinical: Indication for Use claimed by proposed device has been covered by predicate device (K230047 GBOX-20B) which depends on product performance. The descriptions are different, but the contents are the same. And this difference does not affect safety and effectiveness.

Technology: The proposed device uses same 980nm diode lasers technology as that used by the predicates. The output parameters of the proposed device are same to the output parameters of the predicates.

Conclusion: The proposed device uses same diode lasers technology as that used by the predicate. The output parameters of the proposed device are same to the output parameters of the predicates

The indications for use of the subject device claimed by proposed device have been covered by predicate device and also do not raise new types of questions regarding safety and effectiveness.

So, the proposed device is Substantially Equivalent (SE) to existing legally marketed predicate device.

Table6 Substantial equivalence discussion (Medical diode laser systems, Model: CHEESEII-10B)

Item	Proposed device	Co-predicate device (Low Level Laser Therapy)	Discussion
510k Number	/	K230047	/
Proprietary Name	Medical diode laser systems	Medical diode laser systems	/
Model	CHEESEII-10B	CHEESEII-10B	Identical
Product Code	ILY	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	Identical
Classification	Class II	Class II	Identical
Indication for Use	The Medical Diode Laser Systems is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	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.	Identical The descriptions are different, but the contents are the same.
Laser Type	diode laser	diode laser	Identical
Wavelength	980nm±10nm	980 ±10nm	Identical

Output power	0.1W-10W	0.1W-10W	Identical
Energy Density(ED) / (Fluence)	0.05~1.04 J/cm^2 (Per second)	0.05~1.04 J/cm^2 (Per second)	Identical
Power Density	0.05~1.04 W/cm^2	0.05~1.04 W/cm^2	Identical
Spot Diameter	3.5~5 cm	3.5~5 cm	Identical
Working distance	3~5 cm	3~5 cm	Identical
Treatment angle	Perpendicular to the treatment area	Perpendicular to the treatment area	Identical
Applied part moving speed	3~5 cm/s	3~5 cm/s	Identical
Power Accuracy	±20%	(±20%)	Identical
Operation mode	Continuous Wave; Pulse	Continuous Wave; Pulse	Identical
Pulse width	25μs -10s	25μs -10s	Identical
Beam divergence	Working beam: 25° Aiming beam: 25°	Working beam: 25° Aiming beam: 25°	Identical

Treatment methods	Non-contact	Non-contact	Identical
Applied part	Handpiece	Handpiece	Identical
Transmission system	fibers of 600μm with SMA905 connector.	fibers of 600μm with SMA905 connector.	Identical
Aiming Beam	Diode laser of 650nm±10nm, 2mW, adjustable brightness.	650±10nm, 5mw (max).	Different Comment 1
Laser Class	4	4	Identical
Operation interface	Color LCD touch screen	Color touch screen graphical user interface	Identical
Power Supply	Model: MANGO150S-15AK input: 100-240V~ ,2.0-1.0A, 50/60Hz output: 15V ⎓10.0A Max.	Model: MANGO150S-15AK input: 100-240V~ ,2.0-1.0A, 50/60Hz output: 15V ⎓10.0A Max.	Identical
Cooling	Air cooling	Air cooling	Identical
Safety classification	Class I Type B	Class I Type B	Identical

Discussion:

Clinical: Indication for Use claimed by proposed device has been covered by predicate device (K230047 CHEESEII-10B) which depends on product performance. The descriptions are different, but the contents are the same. And this difference does not affect safety and effectiveness.

Technology: The proposed device uses same 980nm diode lasers technology as that used by the predicate. The output parameters of the proposed device are similar to the output parameters of the predicates. The main difference is Aiming beam.

Comment 1 Aiming beam:

The Aiming beam of the proposed device Model CHEESEII -10B (Diode laser of 650nm, power ≤2mW, adjustable brightness) is different to the predicate device (650±10nm, 5mw (max)). But the power is within the scope of what predicate device claims.

Conclusion:

The proposed device uses same diode lasers technology as that used by the predicate. The output parameters of the proposed device are similar to the output parameters of the predicates. The differences only exist in such content: Aiming beam that can be controlled in range of application. The difference is slight in the output parameters do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

The indications for use of the subject device claimed by proposed device have been covered by predicate device and also do not raise new types of questions regarding safety and effectiveness.

So the proposed device is Substantially Equivalent (SE) to existing legally marketed predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

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 IEC60601-1: 2005/AMD1:2012/AMD2:2020 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance).
- Verify the conformity of the proposed devices with the requirements of IEC60601-1-2: 2014+A1:2020 (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 60825-1:2014 (Safety of laser products -Part 1: Equipment classification and requirements).
- Verify the performance of the proposed devices according to IEC 60601-2-22: 2019 (Medical electrical equipment Part 2: Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment).
- Verify the conformity of the proposed devices with the requirements of IEC 60601-1-6: 2010/AMD1:2013/AMD2:2020 (Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability)

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.

Mechanical and acoustic testing

It is not applicable.

Animal Study

It is not applicable.

Clinical Studies

It is not applicable.

VIII. CONCLUSIONS

The Medical Diode Laser Systems 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 devices.