March 19, 2025

Gigaalaser Company Ltd.
Xinxing Nie
Regulations Control Manager
B15-8F, Wuhan Hi-Tech Medical device park,
#818 Gaoxin Road
Wu han, 430206
China

Re: K241791
Trade/Device Name: Medical Diode Laser Systems (GBOX-6H, GBOX-10D , GBOX-12D, GBOX-15D, VELAS Pro-30B15D, VELAS II-6H, VELAS II-15D)
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: GEX
Dated: March 14, 2025
Received: March 14, 2025

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.03.19 07:21:04 -04'00'

for 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.

Submission Number *(if known)*

K241791

Device Name

Medical diode laser systems (GBOX-10D, GBOX-12D, GBOX-15D, GBOX-6H, VELAS Pro-30B15D, VELAS II -6H and VELAS II -15D)

Indications for Use *(Describe)*

(1) The Medical Diode Laser Systems, model: GBOX-6H, VELAS II -6H is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The output wavelength of model GBOX-6H and VELAS II -6H is 1940nm.

(2) The Medical Diode Laser Systems, model: GBOX-10D, GBOX-12D is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endloscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The output wavelength of model GBOX-10D and GBOX-12D is 1470nm.

(3) The Medical Diode Laser Systems, model: GBOX-15D, VELAS II -15D is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The GBOX-15D, VELAS II -15D is further indicated for laser assisted lipolysis. The output wavelength of model GBOX-15D and VELAS II -15D is 1470nm.

(4) The Medical Diode Laser Systems, model: VELAS Pro-30B15D is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. Medical Diode Laser Systems, model: VELAS Pro-30B15D is further indicated for laser assisted lipolysis. The output wavelength of model VELAS Pro-30B15D is 980nm or 1470nm.

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."

510(k) Summary

K241791 Prepared on:2025-03-18

I. SUBMITTER

Device submitter:	Gigaalaser Company Ltd.
Add.:	B15-8F, Wuhan Hi-Tech Medical device park, #818 Gaoxin Road, Wuhan 430206, China
Contact Person:	Name: Xinxing Nie Title: Regulations Control Manager Phone: +86 18062575326 Fax: +86-27-6784 8873 E-mail: fdagigaalaser@sohu.com

Ⅱ. DEVICE

Trade Name of Device:	Medical Diode Laser Systems
Model:	GBOX-6H, VELAS Ⅱ-6H, GBOX-10D, GBOX-12D, GBOX-15D, VELAS Ⅱ-15D, VELAS Pro-30B15D
Regulation name:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Classification name:	POWERED LASER SURGICAL INSTRUMENT
Classification:	Class Ⅱ, 21 CFR 878.4810
Primary Product code:	GEX
Review Panel:	General & Plastic Surgery
510(k) number:	K241791

Ⅲ. PREDICATE DEVICE

Predicate Device

Trade name:	MANTA Diode Lasers
Classification name:	POWERED LASER SURGICAL INSTRUMENT
Regulation number:	21 CFR 878.4810
Regulation name:	GEX-Powered Laser Surgical Instrument, General and Plastic Surgery

Regulatory class:	Class II
Product code:	GEX
Submitter:	SQUALUS MED Ltd.
510(k) number:	K222701

Predicate Device

Trade name:	SkyPulse Laser Platform
Classification name:	POWERED LASER SURGICAL INSTRUMENT
Regulation number:	21 CFR 878.4810
Regulation name:	GEX-Powered Laser Surgical Instrument, General and Plastic Surgery
Regulatory class:	Class II
Product code:	GEX
Submitter:	Fotona d.o.o.
510(k) number:	K193656

Predicate Device

Trade name:	Alma Diode Tabletop Laser
Classification name:	POWERED LASER SURGICAL INSTRUMENT
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:	GEX
Submitter:	Alma Ltd
510(k) number:	K160952

Predicate Device

Trade name:	Medical Diode Laser (M2-GK)
Classification name:	POWERED LASER SURGICAL INSTRUMENT
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:	GEX
Submitter:	Wuhan Pioon Technology Co.,Ltd.
510(k) number:	K240747

IV. DEVICE DESCRIPTION

(1) The “Medical Diode Laser Systems”, include model: GBOX-6H, VELAS Ⅱ-6H, GBOX-10D, GBOX-12D, GBOX-15D, VELAS Ⅱ-15D, VELAS Pro-30B15D which consist of three main components:

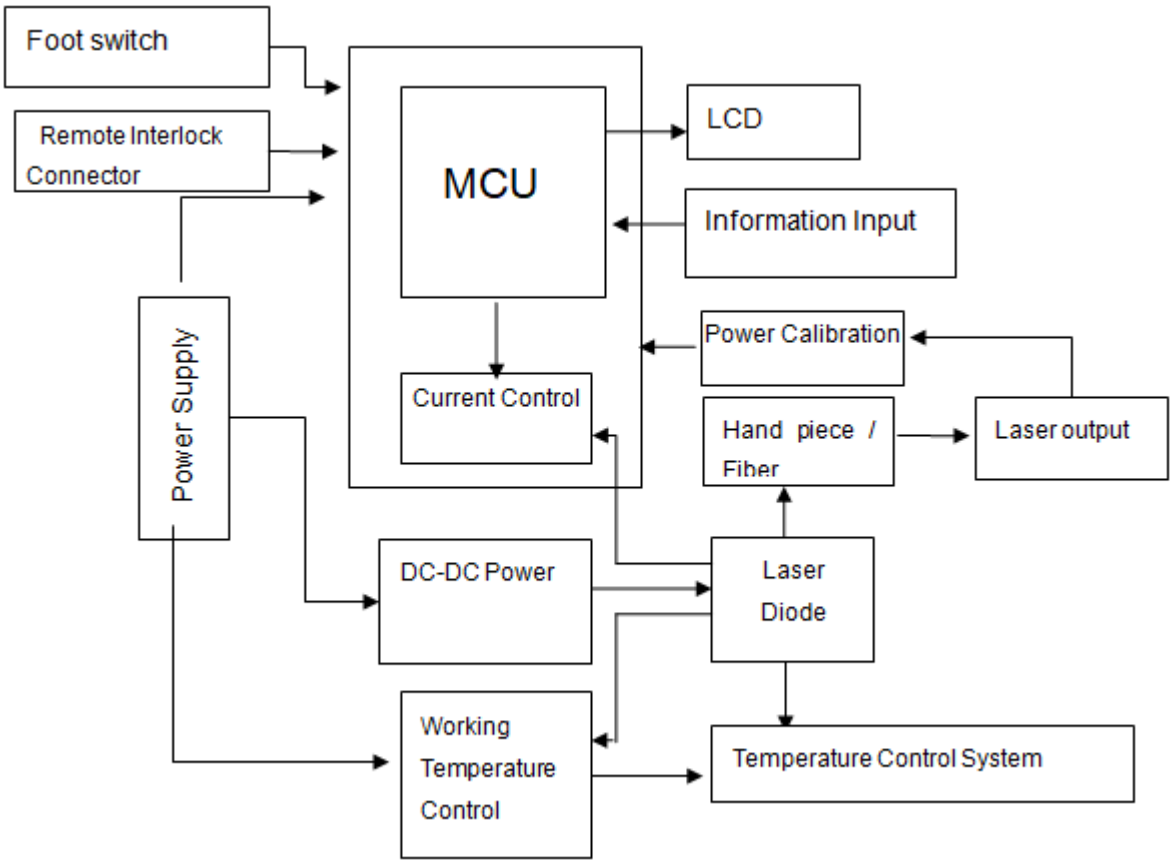
(2) Main device;

(3) 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 1940nm for GBOX-6H, VELAS Ⅱ-6H; 1470nm for GBOX-10D, GBOX-12D, GBOX-15D, VELAS Ⅱ-15D; 980nm or 1470nm for VELAS Pro-30B15D. 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, model: GBOX-6H, VELAS Ⅱ-6H is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The output wavelength of model GBOX-6H and VELAS Ⅱ-6H is 1940nm.

(2) The Medical Diode Laser Systems, model: GBOX-10D, GBOX-12D is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endloscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The output wavelength of model GBOX-10D and GBOX-12D is 1470nm.

(3) The Medical Diode Laser Systems, model: GBOX-15D, VELAS Ⅱ-15D is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The GBOX-15D, VELAS Ⅱ-15D is further indicated for laser assisted lipolysis. The output wavelength of model GBOX-15D and VELAS Ⅱ-15D is 1470nm.

(4) The Medical Diode Laser Systems, model: VELAS Pro-30B15D is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. Medical Diode Laser Systems, model: VELAS Pro-30B15D is further indicated for laser assisted lipolysis. The output wavelength of model VELAS Pro-30B15D is 980nm or 1470nm.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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.

Table 1 Substantial equivalence discussion—GBOX-6H / VELAS Ⅱ-6H

Item	**Proposed device**	**Predicate device (K222701）**	**Predicate device (K193656）**	**Discussion**
	Medical diode laser systems	**MANTA Diode Lasers**	**SkyPulse Laser Platform**	
Product Code	GEX	GEX	GEX	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, model: GBOX-6H, VELAS Ⅱ-6H is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology,	The MANTA1940 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy,	1940 nm Diode Laser: ▪ Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.	Substantial Equivalence Indication for Use claimed by Proposed device is the same with the Predicate device (K222701). Indication for Use claimed by Proposed device has been

	General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.	Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.		covered by Predicate device (K193656).
Laser type	diode laser	diode laser	diode laser	Identical
Wavelength	1940nm	1940nm	1940nm	Identical
Output power	1-6W	Up to 5 W	Up to 7.5W	Similar Comment 1
Pulse width	GBOX-6H: 10ms-10s VELAS Ⅱ-6H: 10ms-10s	10 msec – 30 sec adjustable	CW or 10ms – 10s	Similar Comment 2
Operation Mode	CW, single pulse, repeat pulse	CW, pulsed, single pulse	/	Identical
Operation interface	Color LCD touch screen	Color touch screen	Touch screen control	Identical
Repetition rate	0.05Hz-50Hz	0.02–50Hz	CW or up to 100Hz	Similar Comment 3
Aiming beam	Diode laser of 650nm, power ≤3mW, adjustable brightness. Red, Class1M, CW	Red 635-650nm (＜5mW)	/	Substantial Equivalence
Laser Class	4	4	/	Identical
Power supply	100-240 VAC, 50-60Hz, 200VA	100-240V, 47-63 Hz	/	Substantial

				Equivalence

Discussion:

Clinical: Indication for Use claimed by Proposed device is the same with the Predicate device (K222701). Indication for Use claimed by Proposed device has been covered by Predicate device (K193656). The indication for use depends on product performance and this difference does not affect safety and effectiveness.

Technology: The subject device has the same operation principle and same wavelengths of diode laser to achieve its intended use. The operation mode, Laser Classification, Operation interface are either identical to the predicate. The main differences are Output power, Pulse width and Repetition rate.

Comment 1 Output power:

The power output range of proposed device is 1-6W, which is similar to the predicate device (K222701): 5W; Also similar to Predicate device (K193656): Up to 7.5 W. By Proposed device has been covered by predicate device (K222701) and (K193656).

Comment 2 Pulse width:

The pulse width of the proposed device: 10ms-10s, somewhat different from the predicate device K222701 (10 msec – 30 sec), is within the scope of what predicate device claims. The pulse width of the proposed device: 10ms-10s is the same with the predicate device K193656 (10 ms – 10s).

Comment 3 Pulse Repetition rate:

Repetition rate of the subject device: 0.05Hz-50Hz is within the scope of what predicate device claims. By Proposed device has been covered by Predicate device (K222701) and (K193656).

Material: The fiber in contact with the subject device has been approved in K140470.

Conclusion:

The subject device has the same intended use and operation principal, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices (K222701) and (K193656). The differences between the subject and predicate devices do not alter suitability of the proposed device for its intended use.

Table 2 Substantial equivalence discussion—GBOX-10D / GBOX-12D / GBOX-15D / VELAS Ⅱ-15D

Item	Proposed device	Predicate device (K222701)	Predicate device (K160952)	Discussion
	Medical diode laser systems	**MANTA Diode Lasers**	**Alma Diode Tabletop Laser**	
Product Code	GEX	GEX	GEX	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, model: GBOX-10D/12D is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endloscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and	The MANTA1470 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.	The Alma 1470 nm diode tabletop laser is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Alma 1470 nm diode tabletop laser is further indicated for laser assisted lipolysis.	Substantial Equivalence Indication for Use claimed by Proposed device has been covered by Predicate device (K222701) and (K160952). Indication for Use claimed by Proposed device Medical Diode Laser Systems, model: GBOX-10D/12D is the same with the Predicate device (K222701). Indication for Use

	Dental procedures. Medical Diode Laser Systems, model: GBOX-15D, VELAS Ⅱ-15D is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The GBOX-15D, VELAS Ⅱ-15D is further indicated for laser assisted lipolysis.			claimed by Proposed device Medical Diode Laser Systems, model: GBOX-15D, VELAS Ⅱ-15D is the same with the Predicate device (K160952).
Laser type	diode laser	diode laser	diode laser	Identical
Wavelength	1470nm	1470nm	1470nm	Identical
Output power	GBOX-10D: 1-10W GBOX-12D: 1-12W GBOX-15D: 1-15W	Up to 12 W	Up to 15 W	Similar Comment 1
Pulse width	10ms-10s	10 msec – 30 sec adjustable	10-990ms	Similar Comment 2
Operation Mode	CW, single pulse, repeat pulse	CW, pulsed, single pulse	Continuous wave, single pulse, pulsed	Identical
Operation interface	Color LCD touch screen	Color touch screen	LCD touch screen	Identical
Repetition rate	0.05Hz-50Hz	0.02–50Hz	CW or up to 100Hz	Similar Comment 3
Aiming beam	GBOX-10D/12D/15D: Diode laser of 650nm, power ≤3mW, adjustable brightness. Red, Class 1M, CW;	Red 635-650nm (＜5mW)	635nm	Substantial Equivalence

	VELAS Ⅱ -15D: Diode laser of 650nm, power ≤2mW, adjustable brightness.			
Laser Class	4	4	/	Identical
Power supply	100-240 VAC, 50-60Hz, 200VA	100-240V, 47-63 Hz	/	Substantial Equivalence

Discussion:

Clinical: Indication for Use claimed by Proposed device Medical Diode Laser Systems, model: GBOX-10D/12D is the same with the Predicate device (K222701). Indication for Use claimed by Proposed device Medical Diode Laser Systems, model: GBOX-15D, VELAS Ⅱ -15D is the same with the Predicate device (K160952).

Indication for Use claimed by Proposed device has been covered by Predicate device(K222701) and (K160952) which depends on product performance, and this difference does not affect safety and effectiveness.

Technology: The subject device has the same operation principle and same wavelengths of diode laser to achieve its intended use. The operation mode, Laser Classification, Operation interface are either identical to the predicate. The main differences are Output power, Pulse width and Repetition rate.

Comment 1 Output power:

The Proposed device Medical Diode Laser Systems, model: GBOX-10D/12D has a power output range of 1-10W/1-12W, which is with the scope of what Predicate device (K222701): Max. 12W claims.

The Proposed device Medical Diode Laser Systems, model: GBOX-15D, VELAS Ⅱ-15D has a power output range of 1-15W, which is with the scope of what Predicate device (K160952): Max. 15W claims.

Comment 3 Pulse width:

The pulse width of the subject device: 10ms~10s, somewhat different from the Predicate device (K160952), but within the scope of what Predicate device (K222701) claims.

Comment 3 Repetition rate:

Repetition rate of the subject device: 0.05Hz-50Hz is within the scope of what Predicate device claims. By Proposed device has been covered by Predicate device (K222701) and (K160952).

Material: The fiber in contact with the subject device has been approved in K140470.

Conclusion:

The subject device has the same intended use and operation principle, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices (K222701) and (K160952). The differences between the subject and predicate devices do not alter suitability of the proposed device for its intended use.

Table 3 Substantial equivalence discussion—VELAS Pro-30B15D

Item	Proposed device	Predicate device (K240747）	Discussion
	Medical diode laser systems	**Medical Diode Laser (M2-GK)**	
Product Code	GEX	GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Identical
Classification	Class Ⅱ	Class Ⅱ	Identical
Indication for Use	Medical Diode Laser Systems, model: VELAS Pro-30B15D is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. Medical Diode Laser Systems,	The Medical Diode Laser (Model: M2-GK) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: M2-GK) is further indicated for laser assisted	Identical

	model: VELAS Pro-30B15D is further indicated for laser assisted lipolysis.	lipolysis.	
Laser type	diode laser	diode laser	Identical
Wavelength	980nm; 1470nm	980nm; 1470nm	Identical
Max Output power	980nm: 30W 1470nm: 15W	980nm: 30W 1470nm: 15W	Identical
Pulse width	10ms-1s	10ms-1s	Identical
Operation Mode	CW, single, repeat	CW, single pulse, repeat pulse	Identical
Aiming beam	Diode laser of 635nm power<5mW, and 520nm, power< 3.5mW; adjustable brightness.	Red 650nm (<2mW)	Substantial Equivalence
Cooling	Air	Air	Identical
Laser Class	4	4	Identical
Power supply	100-240 VAC, 50-60Hz, 200VA	100-240VAC, 50/60Hz, 4A-2A	Substantial Equivalence

Discussion:

Technology: The subject device has the same operation principle and same wavelengths of diode laser to achieve its intended use.

The operation mode, Laser Classification, Operation interface and main core technical specifications are either identical to the predicate.

Material: The fiber in contact with the subject device has been approved in K140470.

Conclusion:

The subject device has the same intended use and operation principle, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices (K240747). There are no differences between the subject and predicate devices.

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 Systems.

- Verify the conformity of the proposed devices with the requirements of 2005(R)2012 IEC60601-1 :(Medical electrical equipment Part 1: General requirements for basic safety and essential performance).
- Verify the conformity of the proposed devices with the requirements of 2020-09 IEC60601-1-2 :(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 2007-03 IEC 60825-1 (Safety of laser products - Part 1: Equipment classification and requirements).
- Verify the performance of the proposed devices according to 2012-10 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).
- Verify the conformity of the proposed devices with the requirements of 2020-07 IEC 60601-1-6:(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.