February 20, 2025

Reveal Lasers Ltd.
Mike Collette
Director of Regulatory Affairs and Quality Systems
Raoul Wallenberg 14a, Aviv, Israel, Tel 6971912
Aviv, 64364
Israel

Re: K234004
Trade/Device Name: Medical diode laser systems (CHARISMA, REGAL)
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: [NOTE: Use date of most recent supplement]
Received: February 17, 2025

Dear Mike Collette:

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: 2025.02.20 20:13:22 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234004

Device Name
Medical diode laser systems (CHARISMA, REGAL)

Indications for Use *(Describe)*
The intended use of the "CHARISMA" is:
-Dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.
-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue
-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux
-Further indicated for laser assisted lipolysis.

The intended use of the "REGAL" is:
-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue
-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux
-Further indicated for laser assisted lipolysis.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) summary K234004

Ⅰ Submitter

Device submitter:	Reveal Lasers Ltd.
Add.:	14 Raoul Wallenberg ,Tel Aviv, Israel 6971912
Contact person:	Name: Yoram Levy Qsite, Regulatory Affairs and Quality Systems Tel: +972 (52) 2792871 E-mail: yoram@qsitemed.com

Ⅱ Device

Trade Name of device:	Medical diode laser systems
Model	REGAL, CHARISMA
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
Submission number:	K234004

Ⅲ Predicate Device

Predicate Device 1

Trade name:	LaserME
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:	Neauvia North America
510(k) number:	K230077

Predicate Device 2

Trade name:	Fotona 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 3

Trade name:	Alma Diode Tabletop Laser
Regulation number:	21 CFR 878.4810
Regulation name:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Classification name:	POWERED LASER SURGICAL INSTRUMENT
Regulatory class:	Class Ⅱ
Product code:	GEX
Submitter:	Alma Lasers, Ltd,
510(k) number:	K160952

Reference Predicate Device

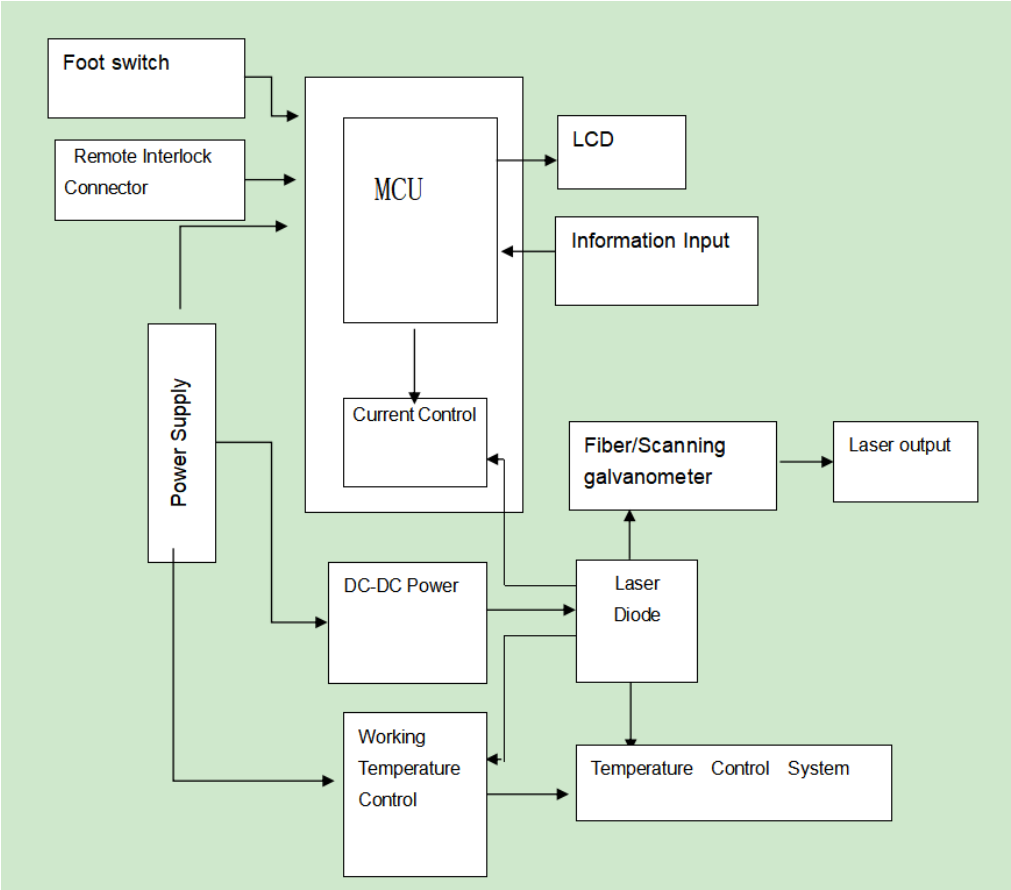
Trade name:	Medical diode laser systems
Classification name:	POWERED LASER SURGICAL INSTRUMENT
Regulation number:	21 CFR 878.4810
Regulation name:	Laser Surgical Instrument for Use in General and Plastic Surgery and In Dermatology
Regulatory class:	Class Ⅱ
Product code:	GEX
Submitter:	Wuhan Gigaa Optronics Technology Co., Ltd
510(k) number:	K160549

Ⅳ Device description

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 1470nm. 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 GIGAA'S 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-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.



The block diagram shows the diode laser system mechanism. 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 the MCU, diode laser module by DC-DC conversion module and temp system by temp-control circuit. The 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.

Specifications

Model: REGAL

(Temperature is 5℃～40℃, relative humidity is no more than 80%, and atmospheric pressure is 860hPa～1060hPa.)

Laser type	GaAlAs diode laser
Model	REGAL
Wavelength	1470nm±10nm
Output power	1-15W(±10%)
***S*t of Output power**	≤10%
***R*p of Output power**	≤10%
Operation mode	CW, single pulse, repeat pulse
Beam divergence	Working beam: 25° Aiming beam: 25°
Pulse width	10ms-2.5s
Pulserepetition rate	0.2Hz-50 Hz
Application systems	Fiber core diameter ≥200μm NA ≥0.22 With SMA905 connector The single used sterile fiber which has already been registered in U.S.A. is applied.
Transmission system	contact: fibers of 200μm, 400μm, 600μm and 1000μm with SMA905 connector; Non-contact: fibers and tips
Aiming beam	Diode laser of 650nm, power＜2mW, adjustable brightness.
Operation interface	Color LCD touch screen
Power supply	~100-240V, 50-60Hz, 350VA

Laser Class	4
Safety classification	Class Ⅰ Type B
Cooling	Air
FUSE	F5AH250VP
Dimensions	440(W)*402(L)*230(H)mm
Weight	13 kg
Waterproof level	IPX1
Footswitch Waterproof level	IPX8
Operating Environment	Temperature is 5℃~40℃, relative humidity is less than 80%, and atmospheric pressure is 860hPa~1060hPa.
Storage Environment	Temperature is -20℃~50℃, relative humidity is less than 80%, and atmospheric pressure is 500hPa~1060hPa.

Model: CHARISMA

(Temperature is 5℃～30℃, relative humidity is no more than 80%, and atmospheric pressure is 860hPa～1060hPa.)

General mode

Laser type	GaAlAs diode laser
Model	CHARISMA
Wavelength	1470nm±10nm
Output power	0.5W-15.0W (±10%)
***S*t of Output power**	≤10%
***R*p of Output power**	≤10%
Operation mode	CW, single pulse, repeat pulse
Beam divergence	Working beam: 25° Aiming beam: 25°
Pulse width	10ms-2.5s
Pulserepetition rate	0.2Hz-50Hz
Application systems	Fiber core diameter ≥200μm NA ≥0.22

	With SMA905 connector The single used sterile fiber which has already been registered in U.S.A. is applied.
Transmission system	contact: fibers of 200μm, 400μm, 600μm with SMA905 connector; Non-contact: fibers
Aiming beam	Diode laser of 650nm, power＜2mW, adjustable brightness.
Operation interface	Color LCD touch screen
Power supply	~100-240V, 50-60Hz, 350VA
Laser Class	4
Safety classification	Class Ⅰ Type B
Cooling	Air
FUSE	F5AH250V
Dimensions	285(W)*370(L)*1035(H)mm
Weight	30 kg
Waterproof level	IPX0
Footswitch Waterproof level	IPX8
Operating Environment	Temperature is 5℃~30℃， relative humidity is less than 80%, and atmospheric pressure is 860hPa~1060hPa.
Storage Environment	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 500hPa~1060hPa.

BeautyScan mode

Laser type	GaAlAs diode laser
Model	CHARISMA
Wavelength	1470nm±10nm
Output power	2W (±10%)
Energy density (energy per microbeam)	up to 50mJ
Number of microbeams	Up to 70
Pulse rate / Repetition rate	0.5-10Hz
Applicator window	5X5 - 18X18mm
Operation mode	Repeat pulse
Beam divergence	Working beam: 25°

	Aiming beam: 25°
Pulse width	10ms-25ms
Operation mode	repeat pulse
Application systems	Scanning galvanometer
Transmission system	contact: fibers of 200μm with SMA905 connector; Non-contact: fibers
Aiming beam	Diode laser of 650nm, power＜2mW, adjustable brightness.
Operation interface	Color LCD touch screen
Power supply	~100-240V, 50-60Hz, 350VA
Laser Class	4
Safety classification	Class Ⅰ Type B
Cooling	Air
FUSE	F5AH250V
Dimensions	285(W)*370(L)*1035(H)mm
Weight	30 kg
Waterproof level	IPX0
Footswitch Waterproof level	IPX8
Operating Environment	Temperature is 5℃~30℃，relative humidity is less than 80%, and atmospheric pressure is 860hPa~1060hPa.
Storage Environment	Temperature is -20℃~55℃, relative humidity is less than 80%, and atmospheric pressure is 500hPa~1060hPa.

Ⅴ Indications for use

The intended use of the “CHARISMA” is:

-Dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.

-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue

-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux

-Further indicated for laser assisted lipolysis.

The intended use of the “REGAL” is:

-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue

-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux

-Further indicated for laser assisted lipolysis.

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.

Table 1 Substantial equivalence discussion -- CHARISMA

Item	Proposed device	Predicate device 1 （K230077）	Predicate device 2 （K193656）	Predicate device 3 (K160952）	Reference Predicate device （K160549）	Discussion
	Medical diode laser systems	LaserME	Fotona SkyPulse Laser Platform	Alma 1470nm diode tabletop laser	VELAS Ⅱ-15D	
Product Code	GEX	GEX	GEX	GEX	GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Classification	Class II	Class II	Class II	Class II	Class II	Identical
Indication for Use	-Dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines. -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue -Endovascular coagulation and	The LaserMe is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. The LaserMe is further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.	1470 nm Diode Laser: -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue - Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux	-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.	VELAS Ⅱ-15D" is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	Substantial Equivalence Indication for Use claimed by Proposed device has been covered by Predicate device (K230077), (K193656), (K160952) and (K160549).

	endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux -Further indicated for laser assisted lipolysis.					
Laser Classification	diode laser	diode laser	diode laser	diode laser	diode laser	Identical
Wavelength	1470nm±10nm	1470 ±20nm	1470nm	1470nm	1470nm	Identical
Energy density (energy per microbeam) (BeautyScan Mode)	up to 50mJ	up to 50mJ	/	/	/	Identical
Number of microbeams (BeautyScan Mode)	up to 70	up to 70	/	/	/	Identical
Applicator window in (mm) (BeautyScan Mode)	5X5 - 18X18mm	12x12mm	/	/	/	Similar
Output power	General Mode: 0.5W-15.0W (±10%) BeautyScan Mode: 2W (±10%)	Up to 2 W	Up to 22 W	15W	1-15W	General Mode: Similar; BeautyScan Mode: substantially equivalent (within the range of K230077); clinical needs can be met.
Pulse width	10ms-2.5s (General mode) 10ms-25ms (beautyScan mode)	3ms~30ms	10ms – 10 s	10-990ms	10ms-2.5s	Similar

Operation Mode	CW, single pulse, repeat pulse (General mode) Repeat pulse (beautyScan mode)	pulse	CW	Continuous wave, single pulse, pulsed	CW, single pulse, repeat pulse	Identical
Operation interface	Color LCD touch screen	LCD touch screen	Touch screen control	LCD touch screen	Color LCD touch screen	Identical
Repetition rate	General Mode: 0.2Hz-50 Hz BeautyScan Mode: 0.5-10Hz	Up to 18 Hz	CW or up to 100 Hz	/	0.2Hz-50Hz	Similar
Aiming Beam	Diode laser of 650nm, power ＜ 2mW, adjustable brightness.	/	/	635nm	Diode laser of 635/532nm, power max. ＜ 5mW, adjustable brightness	Identical
Delivery system	Fiber delivery	Fiber delivery	Fiber delivery	Fiber delivery	Fiber delivery	Identical
Power Supply	~100-240V, 50-60Hz, 350VA	112-240 VAC, 50/60Hz	/	100-240, V AC 50-60 Hz	100-240VAC, 50/60Hz, 350VA	Similar

Discussion:

As for General mode:

Clinical: Indication for Use claimed by Proposed device has been covered by Predicate device (K160952), (K160549) and (K193656) 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 or the reference device. The main differences are output power, pulse width and repetition rate.

-Output power: The Proposed device has a power output range of 0.5W-15.0W, similar to Predicate device (K160549); also, similar to Predicate device (K160952): 15W.

-Pulse width: The pulse width of the subject device: 10ms-2.5s, which is identical to the Reference device (K160549); Somewhat different from Predicate device, but within the scope of what Predicate device claims.

-Repetition rate: Repetition rate of the subject device: 0.2Hz-50Hz, which is identical to the Reference device(K160549), Somewhat different from Predicate device, but within the scope of the Predicate device claim.

As for BeautyScan Mode

Clinical: Indication for Use claimed by the proposed device has been covered by Predicate device (K230077) which depends on product performance and this difference does not affect safety and effectiveness.

Technology:

The subject device has the same laser classification, wavelength, same operation mode, energy density (energy per microbeam) and number of microbeams to achieve its intended use. (Compare with the K230077).

The comparative analysis of core technical parameters is as follows:

-Applicator window in (mm): applicator window of the subject device is 5X5-18X18mm, predicate device K230077 is 12x12mm. The minimum applicator window of subject device is smaller than the predicate device. The maximal applicator window of subject device is slightly bigger than the predicate device. The subject device has more precise treatment area. But all of them are intended to meet clinical needs, and it doesn't raise different questions of safety and effectiveness than the predicate device. Therefore, it is substantially equivalent.

-Output power: output power of the subject device is 2W, predicate device K230077 is up to 2W. The output power of the subject device is within the range of the predicate device (K230077). All of them are intended to meet clinical needs, and it doesn't raise different questions of safety and effectiveness than the predicate device. Therefore, it is substantially equivalent.

-Pulse width: pulse width of the subject device is 10ms- 25ms, predicate device K230077 is 3~30ms. The pulse width of the subject device is within the range of predicate device (K230077). The pulse width is intended to meet clinical needs, and it doesn't raise different questions of safety and effectiveness than the predicate device. Therefore, it is substantially equivalent.

-Repetition rate: repetition rate of the subject device is 0.5-10Hz, predicate device K230077 is up to 18 Hz. The repetition rate of subject device is within the range of predicate device (K230077). The repetition rate is intended to meet clinical needs, and it doesn't raise different questions of safety and effectiveness than the predicate device. Therefore, it is substantially equivalent.

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. 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 -- REGAL

Item	Proposed device	Predicate device (K193656)	Predicate device (K160952)	Predicate device (K160549)	Discussion
	Medical diode laser systems	SkyPulse Laser Platform	Alma 1470nm diode tabletop laser	VELAS Ⅱ-15D	
Product Code	GEX	GEX	GEX	GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Classification	Class II	Class II	Class II	Class II	Identical
Indication for Use	- Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue - Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux - Further indicated for laser assisted lipolysis.	1470 nm Diode Laser: - Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue -Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux	-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.	VELAS Ⅱ -15D is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	Substantial Equivalence Indication for Use claimed by Proposed device has been covered by Predicate device(K160952), (K160549) and (K193656).
Laser Classification	diode laser	diode laser	diode laser	diode laser	Identical
Wavelength	1470nm+10nm	1470nm	1470nm	1470nm	Identical

Output power	1-15W(±10%)	Up to 22 W	15w	1-15W	Similar
Pulse width	10ms-2.5s	10ms – 10s	10-990ms	10ms-2.5s	Similar
Operation Mode	CW, single pulse, repeat pulse	CW	Continuous wave, single pulse, pulsed	CW, single pulse, repeat pulse	Substantial Equivalence
Operation interface	Color LCD touch screen	Touch screen control	LCD touch screen	Color LCD touch screen	Identical
Repetition rate	0.2Hz-50 Hz	CW or up to 100 Hz	/	0.2Hz-50Hz	Similar
Aiming Beam	Diode laser of 650nm, power ＜ 2mW, adjustable brightness.	/	635nm	Diode laser of 635/532nm, power max. ＜ 5mW, adjustable brightness	Similar
Delivery system	It is recommended to use the disposable sterile fiber (K140470, OBERON GmbH Fiber Technologies) registered in U.S.A. The fiber parameter must satisfy the following: Bare fiber, long as 3m Fiber core diameter: 200μm/400μm/600μm NA ≥0.22 With SMA905 connector Single used	Fiber delivery	Alma Diode Tabletop Laser	It is recommended to use the disposable sterile fiber (K124003, MED-Fibers, Inc.) registered in U.S.A. The parameters must meet the following requirements: Bare fiber, long as 3m Fiber core diameter: 600μm NA ≥0.22 With SMA905 connector Single used	Similar
Power Supply	~100-240V, 50-60Hz, 350VA	/	100-240, V AC 50-60 Hz	100-240VAC, 50/60Hz, 350VA	Similar

Discussion:

Clinical: Indication for Use claimed by Proposed device has been covered by Predicate device (K160952), (K160549) and (K193656) 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 or the reference device. The main differences are output power, pulse width and repetition rate.

-Output power: The Proposed device has a power output range of 1W-15.0W, same as Predicate device (K160549), and similar to Predicate device (K160952): 15W.

-Pulse width: The pulse width of the subject device: 10ms-2.5s, which is identical to the Reference device (K160549); Somewhat different from Predicate device, but within the scope of the Predicate device claim.

-Repetition rate: Repetition rate of the subject device: 0.2Hz-50Hz, which is identical to the Reference device (K160549), somewhat different from Predicate device, but within the scope of what predicate device claims

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. The differences between the subject and predicate devices do not alter suitability of the proposed device for its intended use.

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 IEC60601-1: 2005/(R)2012 (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: 2014-02 (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: 2007-03 (Safety of laser products - Part 1: Equipment classification and requirements).

- Verify the performance of the proposed devices according to IEC 60601-2-22: 2012-10 (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.