DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 7, 2017

Wuhan Gigaa Optronics Technology Co., Ltd
Nie Xinxing
Regulation Control Manager
5, 6/F, Unit A, B, Building B8, Hi-tech Medical Device
Industrial Park, #818 Gaoxin Avenue
East Lake Development Zone, Wuhan, 430206 CN

Re: K160549
Trade/Device Name: Medical Diode Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 27, 2017
Received: March 6, 2017

Dear Nie Xinxing:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160549

Device Name
Medical Diode Laser Systems

Indications for Use *(Describe)*
The "VELASⅡ-15D" is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

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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Section 5 - 510(k) Summary

Date of Summary Preparation: February 22, 2016
Date of Summary Revision: February 27, 2017

1. Submitter's Identifications

Submitter's Name: Wuhan Gigaa Optronics Technology Co., Ltd
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2. Correspondent's Identifications

Correspondent's Name: Wuhan Gigaa Optronics Technology Co., Ltd
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Contact Person: Nie Xinxing
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3. Name of the Device

Device Classification Name: POWERED LASER SURGICAL INSTRUMENT
Product Name: POWERED LASER SURGICAL INSTRUMENT
Trade Name: Medical diode laser systems
Model: VELAS Ⅱ-15D
Classification Panel: General & Plastic Surgery
Product Code: GEX
Device Classification: Class II

4. The Predicate Devices

K082225 15W Ceralas D 1470nm Diode Laser, D1470

5. Device Description

Medical diode laser systems are a kind of laser with semiconductor as working material. It consists of working material, cavity resonator and power source.
The medical diode laser systems for this unit is GaAlAs diode bar, and the wavelength is 1470nm of VELAS Ⅱ-15D. It features impact structure, high efficiency and long lifetime. The beam divergence angle is too large lead to poor beam quality. In order to better meet the needs of Laser

Diode practical applications, Laser Diode carried beam shaping is very necessary. With the GIGAA'S unique fiber-coupling technology, the laser beam can be coupled efficiently into the fiber.

To start the laser unit, turn the main switch ON and turn the key switch clockwise to "I" position. The power indicator will turn green immediately with the system fans working. At the same time, the LCD screen lights up.

After the parameters setting is finished, press the "Ready" button and the system will remind you to wear the protective eyewear (protective wavelength is from 800nm to 1700nm). At this time when you press down the footswitch, the laser will emit.

6. Intended Use of Device

Intended Use of Medical Diode Laser Systems "VELASⅡ-15D" is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

7. Summary of Substantial Equivalence

Table 1

	Proposed Device	Predicate device	Comparison
510k Number	-------	K082225	------
Product Code	GEX	GEX	Same
Proprietary Name	Medical Diode Laser Systems	15W Ceralas D 1470nm Diode Laser	------
Model	VELASⅡ-15D	D1470	------
Manufacturer	Wuhan Gigaa Optronics Technology Co., Ltd	Biolitec, Inc.	------
Indications for use	The "VELASⅡ-15D" is indicated for use in the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	Same
Laser Type	diode laser	diode laser	Same
Components	Laser system, Color touch screen, Foot switch, Power detector	Laser system, Color touch screen, Fiber and the handpiece, Foot switch, Power detector	Similar. Handpiece in D1470 as the laser transmission system used with optical fiber together. VELASⅡ-15D does not equip with fiber and handpiece, but recommending a

			disposable sterile fiber (K124003, MED-Fibers, Inc.) registered in U.S.A, not affect the safety and effectiveness.
Wavelength	1470nm±10nm	1470nm±30nm	Similar. Center wavelength is consistent, and wavelength accuracy of VELAS Ⅱ-15D is better than that of the predicate device.
Output power	1-15W	1-15W	Same
Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Same
Pulse width	10ms-2.5s	0.01s -60s	Similar. Pulse width range of the device is contained in that of the predicate device, and it has been designed to meet the intended use requirement claimed.
Pulse repetition rate	0.2Hz-50Hz	0.01Hz-50Hz	Similar. Pulse repetition rate is slight similar, not affact safety and effectiveness.
Application / Light delivery system	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	Fiber diameter ≥ 360μm	Similar. VELAS Ⅱ-15D is described more detailed. Fiber core diameter range of VELAS Ⅱ-15D is contained in that of the predicate device, and it has been designed to meet the intended use requirement claimed.

Aiming Beam	Diode laser of 635/532nm, power max. ＜ 5mW, adjustable brightness.	532nm and 635nm, green 1mW, red 4 mW, user controlled intensity	Similar. Aiming beam power range of VELAS Ⅱ-15D contains that of the predicate device, and it has been designed to meet the intended use requirement claimed.
Laser Class	4	4	Same
Operation interface	Color LCD touch screen	Color LCD touch screen	Same
Power Supply	100-240VAC, 50/60Hz, 350VA	220-240 VAC, 50/60Hz, 450VA	Similar. Only rated power is different, not affect safety and effectiveness.
Safety classification	Class Ⅰ Type B	Class Ⅰ Type B	Same
Dimensions	400(W)*385(L)*200(H) mm	370(W)*90(L)*280(H) mm	Similar. VELAS Ⅱ-15D is bigger than the predicate device.
Weight	12.9kg	8.5kg	Similar. VELAS Ⅱ-15D is heavier than the predicate device.
Waterproof level	IPX1	IPX1	Same
Footswitch Waterproof level	IPX8	IPX8	Same
Standard	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	Same
Non- sterile	Fiber is sterilized by EO.	Fiber is sterilized by EO.	Same
Microprocessor Control	Yes	Yes	Same

8. Substantial Equivalence:

The proposed device of VELAS Ⅱ-15D has the same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device.

The differences only exist in such contents: component of handpiece that do not influence use even if without it, wave rang of wavelength, output power, pulse width, pulse repetition rate and aiming beam that all can be controlled in range of application. These differences are slight and do not influence the effectiveness and safety of the device. According to the non-clinical and clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.

9. Non-Clinical Tests Performed:

The following testing was performed on the "VELAS Ⅱ-15D" Medical Diode Laser Systems in accordance with the requirements of the design control regulations and established quality assurance procedures.

IEC60601-1:2005+A1:2012+National differences of US ANSI/AAMI Medical electrical equipment-Part 1: General requirements for basic safety and essential performance Incorporates Amendment 1:2012; Incorporates National differences of US ANSI/AAMI

ES60601-1:2005+C1:2009+A2:2010+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance Consolidated reprint C1:2009; Incorporates Amendment 2:2010; Incorporates Amendment 1:2012

IEC60601-2-22:2007+A1:2012 Medical electrical equipment-Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment Incorporates Amendment 1:2012

IEC60601-1-2:2007 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC60825-1:2007 Safety of laser products-Part 1: Equipment classification and requirements

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

10. Conclusion:

The proposed devices of VELAS Ⅱ-15D is determined to be Substantially Equivalent (SE) to the predicate device, 15W Ceralas D 1470nm Diode Laser, D1470 in respect of safety and effectiveness.

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