November 14, 2024

Wontech Co., Ltd.
Hyunsik Yoon
Regulatory Affairs Team General Manager
64 Techno 8-Ro, Yuseong-Gu
Daejeon, 34028
Korea, South

Re: K241930
Trade/Device Name: Veincare
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: July 1, 2024
Received: July 1, 2024

Dear Hyunsik Yoon:

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: 2024.11.14 21:45:34 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K241930

Device Name
Veincare

Indications for Use *(Describe)*
Veincare is intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb

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.

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510(k) Summary (K241930)

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

November 6, 2024

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: WON TECH Co., Ltd.
- Address: 64 Techno 8-ro, Yuseong-gu, Daejeon, 34028, Republic of Korea
- Contact Name: Hyun Sik Yoon
- Telephone No.: +82 42 934 6800
- Fax No.: +82 42 934 9491
- Email Address: regulatory@wtlaser.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Surgical Diode Laser System
Trade name: Veincare

Classification Description	21 CFR Section	Product Code
Laser surgical instrument for use in general and plastic surgery and in dermatology	878.4810	GEX

As stated in 21 CFR, parts 878.4810, this generic type of devices has been classified as Class II.

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device 1

- 510(k) Number: K181632
- Applicant: Quanta System Spa

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- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: VenaCure 1470 Pro

Predicate device 2

- 510(k) Number: K160549
- Applicant: Wuhan Gigaa Optronics Technology Co., Ltd.
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: VELASII-15D

5. Description of the Device [21 CFR 807.92(a)(4)]

The Veincare laser system consists of a Laser Diode module, a power supply and a cooling system. The laser diode module consists of an optical sensor interface, fiber connector for high power SMA fiber, protective glass holder, monitoring interface, cathode and anode. The system delivers laser energy at a wavelength of 1470nm. The output of the laser is delivered to the area of treatment through an optical fiber cable a trigger (Foot switch) controls the delivery of pulses. The user selects the desired energy density and enables or disables the laser at the touched LCD panel.

6. Statement of intended use [21 CFR 807.92(a)(5)]

The Veincare is intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb

7. Summary of Technological Characteristics [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the Veincare and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device 1	Predicate Device 2	SE Decision
K Number	-	K181632	K160549	-
Manufacturer	WON TECH Co., Ltd.	Quanta System Spa	Wuhan Gigaa Optronics Technology Co., Ltd.	-
Model	Veincare	VenaCure 1470 Pro	Medical Diode Laser System	-
Intended Use	Veincare is intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous	intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the	Indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities	Same as 1, similar to 2

	Proposed Device	Predicate Device 1	Predicate Device 2	SE Decision
	Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb	treatment of incompetent refluxing veins in the superficial venous system in the lower limb		
Principle/ Method of Operation	The Veincare laser system consists of a Laser Diode module, a power supply and a cooling system. The laser diode module consists of an optical sensor interface, fiber connector for high power SMA fiber, protective glass holder, monitoring interface, cathode and anode. The system delivers laser energy at a wavelength of 1470nm. The output of the laser is delivered to the area of treatment through an optical fiber cable a trigger (Foot switch) controls the delivery of pulses. The user selects the desired energy density and enables or disables the laser at the touched LCD panel.	The VenaCure 1470 Pro is a diode laser system emitting at 1470 nm wavelength, with maximum output power 15 W. Only the use of optical fibers manufactured by AngioDynamics (provided with RFID tag with proprietary internal code) is allowed with the Any other use is forbidden. The front panel of the device includes the touch screen display, the optical fiber connector (SMA 905) with the RFID antenna, the external protection shutter and the sliding knob. On the rear panel the footswitch connector, the key switch, the remote interlock and the main switch are located. The emergency stop button is on the upper part of the device	The medical diode laser systems for this unit is GaAlAs diode bar, and the wavelength is 1470nm of VELASII-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.	Same as 1 and 2
Maximum Power Output	0.5~15W	15W	1~15W	Same as 1 and 2
Wavelength	1470nm	1470nm	1470nm	Same as 1 and 2
Pulse Repetition	1Hz ~ 500Hz	Up to 2000Hz	0.2 Hz ~ 50Hz	Similar to1 and 2, does not affect safety and efficacy
Pulse duration	0.2ms ~ 800ms	Up to 10,000ms	10ms ~ 2500ms	Similar to 2, does not affect safety and efficacy
Mode of Operation	CW, pulsed, Group pulsed	CW, pulsed	CW, single pulse, repeat pulse	Same as 1 and 2

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Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Electrical Safety, Electromagnetic Compatibility Testing

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety

- IEC 60601-1-6 Edition 3.1 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance

- IEC 60601-2-22:2007/A:2012 Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance

- IEC 60825-1 Edition 3.0 2014 Safety of laser products - Part 1: Equipment classification, and requirements

- IEC 60601-1-2:2014/A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perform

2) Software Validation

The Veincare contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

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3) Biocompatibility

- The part of the device that comes into contact with the human body is the optical fiber. However, the optical fiber that is a component of the device has received 510(k) clearance beforehand (e.g., K232106). Therefore, no additional biocompatibility test report is needed.

4) Performance Testing

The performance of the Veincare has been defined as follows.

- Laser wavelength: 1470nm
- Laser output power: 0.5 to 15 W
- Pulse /duration: Pulse mode: (0.2 to 800)ms
  Group pulse mode: (0.2 to 800)ms
  CW mode: CW
- Pulse frequency: 1-500Hz

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification WON TECH Co., Ltd. concludes that the Veincare is substantially equivalent to predicate devices as described herein.