WON TECH Co., Ltd.
Hyun Sik Yoon
Official Correspondent
64 Techno 8-ro, Yuseong-Gu
Daejeon, 34028
Korea, South

August 24, 2022

Re: K221427
Trade/Device Name: V-Laser
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: May 6, 2022
Received: July 26, 2022

Dear Hyun Sik 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 (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Neil R.P. Ogden, MS
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)*
K221427

Device Name
V-Laser

Indications for Use *(Describe)*
The V-Laser laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

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

[As required by 21 CFR 807.92]

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

May 6, 2022

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.: +82-10-6750-5346
- Fax No.: +82-70-7836-0110
- Email Address: yoonhs21@wtlaser.com

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

Common name: Powered Laser Surgical System
Trade name: V-Laser

Classification Description	21 CFR Section	Product Code
Powered Laser Surgical Instrument	878.4810	GEX

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

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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

- 510(k) Number: K183156
- Applicant: WON TECH Co., Ltd.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: V-Laser

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

The V-Laser is a Nd:YAG laser operating at wavelengths of 1,064 nm and 532 nm. The V-Laser consists of the main body, optical fiber cable, user-undetachable laser handpiece, handpiece tip, footswitch, and handpiece cable cradle. The laser output is delivered to the skin through the optical fiber terminated by the handpiece. The fluence (energy density), frequency and pulse are controlled from the LCD display/Touch Pad located on the front of the main unit. The LCD display is used to obtain feedback from the system, such as the number of pulses delivered or spot size selected.

For treatment, the user can select the appropriate fluence value. The energy is changed automatically in accordance with the selected fluence value and selected spot size. The user can change the fluence value by pressing  (up) and/or  (down) button.
The selectable fluence values are 2 to 300 J/cm2 at 1064 nm and 1.8 to 42 J/cm2 at 532 nm.

Wavelength	1064 nm	532 nm	Genesis Mode
Fluence Value(J/cm^2)*	0.2 - 10.0**	0.1 - 2.5**	4 – 7**

The formula used to calculate the fluence is as follows:
*Fluence[J/cm2] = Energy [J]/((Spot Size/2[cm])2 * 3.14).
** Laser output is limited by software depending on the selected spot size (2 – 20 mm).

6. Indications for Use [21 CFR 807.92(a)(5)]

The V-Laser laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

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7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the previous and renewed V-Laser 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		SE Decision
K Number	-		K183156		N/A
Manufacturer	WON TECH Co., Ltd.		WON TECH Co., Ltd.		Same
Model	V-laser		V-Laser		Same
Indications for Use	The V-Laser laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.		The V-Laser laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.		Same
Anatomical site	Skin and subcutaneous tissue		Skin and subcutaneous tissue		Same
Principle/Method of Operation	The V-Laser is a Nd:YAG laser operating at wavelengths of 1,064 nm and 532 nm. The V-Laser consists of the main body, optical fiber cable, user-undetachable laser handpiece, handpiece tip, footswitch, and handpiece cable cradle. The laser output is delivered to the skin through the optical fiber terminated by the handpiece. The fluence (energy density), frequency and pulse are controlled from the LCD display/Touch Pad located on the front of the main unit. The LCD display is used to obtain feedback from the system, such as the number of pulses delivered or spot size selected.		The V-Laser is a Nd:YAG laser operating at wavelengths of 1,064 nm and 532 nm. The V-Laser consists of the main body, optical fiber cable, user-undetachable laser handpiece, handpiece tip, footswitch, and handpiece cable cradle. The laser output is delivered to the skin through the optical fiber terminated by the handpiece. The fluence (energy density), frequency and pulse are controlled from the LCD display/Touch Pad located on the front of the main unit. The LCD display is used to obtain feedback from the system, such as the number of pulses delivered or spot size selected. The Skin Cooling Spray(SCS) protects the upper layers of the skin with a cooling burst of cryogen.		Difference (Gas cooling has been removed from the renewaled V-Laser)
Wavelength	1064 nm	532 nm	1064 nm	532 nm	Same

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	Proposed Device	Predicate Device #1	SE Decision
Spot Size	1064 nm: 2 to 12 mm 532 nm: 2 to 12 mm' Genesis: 8mm	1064 nm: 2 to 20 mm 532 nm: 2 to 20 mm' Genesis: 8mm	Different This change has no effect regarding the intended of use, safety, and effectiveness, as the tip of the renewed handpiece is all included in the previous specification.
Output	1064 nm: Max. 50 J 532 nm: Max. 10 J	1064 nm: Max. 50 J 532 nm: Max. 10 J	Same
Fluence	1064 nm: 2 to 300 J/cm^2 532 nm: 1.8 to 42 J/cm^2 Genesis Mode: 4 to 7 J/cm^2	1064 nm: 2 to 300 J/cm^2 532 nm: 1.8 to 42 J/cm^2 Genesis Mode: 4 to 7 J/cm^2	Same
Pulse Duration	1064 nm: Max. 60 ms 532 nm: Max. 40 ms Genesis Mode: Max. 0.3 ms	1064 nm: Max. 60 ms 532 nm: Max. 40 ms Genesis Mode: Max. 0.3 ms	Same
Repetition Rate	Max. 10 Hz	Max. 10 Hz	Same
Laser Media	Flashlamp-pumped solid state rod	Flashlamp-pumped solid state rod	Same
Aiming Beam	635 nm	635 nm	Same
Cooling System	Contact cooling system	Contact cooling system Gas cooling system	Different Gas cooling has been removed.

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

The renewed V-Laser has been conducted required test with the current available standards,

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:

Standard (Edition)	Standard Title
AASI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
ANSI AAMI IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6 Edition 3.1 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-22 Edition 4 2014	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1:2014 (Third Edition	Safety of laser products - Part 1: Equipment classification and requirements

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2) Software Validation

The V-Laser 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.

3) Biocompatibility

Part	**Material**	**Patient Contact**	**Duration of Contact by ISO 10993-1**	**Bio-compatibility**
Handpiece Tip	Stainless Steel	Intact Skin	Limited (< 24 hours)	Yes
	Sapphire Window			

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- The material of handpiece for the V-Laser is same to previous registered material of own product (V-Laser <510k number: K183156>)

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 V-laser is substantially equivalent to previous device (V-Laser, K183156) as described herein.