August 14, 2023

WON TECH Co., Ltd.
Hyun Yoon
General Manager
64 Techno 8-ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K231054
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: April 11, 2023
Received: April 13, 2023

Dear Hyun 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,

Jianting Wang -S

For Tanisha L. Hithe
Acting 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)*
K231054

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.

1064 nm:
Dermatology:
The V-Laser is intended for the coagulation ans hemostasis of benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venus lake, leg veins, spider veins, and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as, but not limited to, warts, scars, striae, and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions, such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos), and plaques.

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The V-Laser is also indicated for the treatment of wrinkles, such as, but not limited to, periocular and perioral wrinkles.

The V-Laser is indicated for temporary and permanent hair reduction. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime.

The V-Laser is also indicated for the treatment for pseudofolliculitis barbae.

The V-Laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The V-Laser is also indicated for treatment of mild to moderate inflammatory acne vulgaris.

The intended use of the cooling system in the V-Laser handpiece is to provide cooling of the skin prior to laser treatment; for the reduction of pain during laser treatment; to allow for the use of higher fluences for laser treatments, such as hair removal and vascular lesions; and to reduce the potential side effects of laser treatments.

532 nm:
For coagulation and hemostasis of vascular and cutaneous lesions in dermatology, including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

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)]

April 11, 2023

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#1

- 510(k) Number: K221427
- Applicant: WON TECH Co., Ltd.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: V-Laser

Predicate device #2

- 510(k) Number: K153671
- Applicant: CUTERA, INC.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: Family of CoolGlide Aesthetic Lasers

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 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 – 12 mm).

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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.

1064 nm:

Dermatology:

The V-Laser is intended for the coagulation ans hemostasis of benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venus lake, leg veins, spider veins, and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as, but not limited to, warts, scars, striae, and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions, such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos), and plaques.

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The V-Laser is also indicated for the treatment of wrinkles, such as, but not limited to, periocular and perioral wrinkles.

The V-Laser is indicated for temporary and permanent hair reduction. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime.

The V-Laser is also indicated for the treatment for pseudofolliculitis barbae.

The V-Laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The V-Laser is also indicated for treatment of mild to moderate inflammatory acne vulgaris.

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The intended use of the cooling system in the V-Laser handpiece is to provide cooling of the skin prior to laser treatment; for the reduction of pain during laser treatment; to allow for the use of higher fluences for laser treatments, such as hair removal and vascular lesions; and to reduce the potential side effects of laser treatments.

532 nm:

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology, including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

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

	Proposed Device	Predicate Device #1	Predicate Device #2	Differences
K Number	-	K221427	K153671	
Manufacturer	WON TECH Co., Ltd.	WON TECH Co., Ltd.	CUTERA, INC.	
Model	V-laser	V-laser	Family of CoolGlide Aesthetic Lasers	
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. 1064 nm: Dermatology: The V-Laser is intended for the coagulation and hemostasis of benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venus lake, leg veins, spider veins, and poikiloderma of civatte; and treatment of benign cutaneous	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.	Family of CoolGlide is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. 1064 nm: Dermatology: Family of CoolGlide is intended for the coagulation and hemostasis of benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venus lake, leg veins, spider veins, and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as, but not limited to, warts, scars, striae,	The proposed device's laser treatment wavelengths and relevant laser output ranges are considered to be the same as those of the K153671 device.

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	Proposed Device	Predicate Device #1	Predicate Device #2	Differences
	lesions, such as, but not limited to, warts, scars, striae, and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions, such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos), and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. The V-Laser is also indicated for the treatment of wrinkles, such as, but not limited to, periocular and perioral wrinkles, The V-Laser is indicated for temporary and permanent hair reduction. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime. The V-Laser is also indicated for the		and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions, such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos), and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. Family of CoolGlide is also indicated for the treatment of wrinkles, such as, but not limited to, periocular and perioral wrinkles, Family of CoolGlide is indicated for temporary and permanent hair reduction. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime. Family of CoolGlide is also indicated for the treatment for pseudofolliculitis barbae.	

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	Proposed Device	Predicate Device #1	Predicate Device #2	Differences
	treatment for pseudofolliculitis barbae. The V-Laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. The V-Laser is also indicated for treatment of mild to moderate inflammatory acne vulgaris. The intended use of the cooling system in the V-Laser handpiece is to provide cooling of the skin prior to laser treatment; for the reduction of pain during laser treatment; to allow for the use of higher fluences for laser treatments, such as hair removal and vascular lesions; and to reduce the potential side effects of laser treatments. 532 nm: For coagulation and hemostasis of vascular and cutaneous lesions in dermatology, including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines,		Family of CoolGlide is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Family of CoolGlide is also indicated for treatment of mild to moderate inflammatory acne vulgaris. The intended use of the cooling system in the CoolGlide handpiece is to provide cooling of the skin prior to laser treatment; for the reduction of pain during laser treatment; to allow for the use of higher fluences for laser treatments, such as hair removal and vascular lesions; and to reduce the potential side effects of laser treatments. 532 nm: For coagulation and hemostasis of vascular and cutaneous lesions in dermatology, including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis,	

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	Proposed Device		Predicate Device #1		Predicate Device #2		Differences
	chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).				color lightening, blanching, flattening, reduction of lesion size).		
Anatomical site	Skin and subcutaneous tissue		Skin and subcutaneous tissue		Skin and subcutaneous tissue		Same
Wavelength	1064 nm	532 nm	1064 nm	532 nm	1064 nm	532 nm	Same
Spot Size	1064 nm: 2 to 12 mm 532 nm: 2 to 12 mm' Genesis: 8mm		1064 nm: 2 to 12 mm 532 nm: 2 to 12 mm' Genesis: 8mm		1064 nm: 3 to 18 mm 532 nm: 2 to 12 mm Genesis Mode: 8 mm		The proposed device's smaller spot size range for the 1064 nm output does not raise new considerations for safety and effectiveness compared to the K153671 device.
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/cm2 532 nm: 1.8 to 42 J/cm2 Genesis Mode: 4 to 7 J/cm2		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		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		Max. 10 Hz		Same
Laser Media	Flashlamp-pumped solid state rod		Flashlamp-pumped solid state rod		Flashlamp-pumped solid state rod		Same
Aiming Beam	635 nm		635 nm		630 to 680 nm		Difference in the wavelengths does not

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	Proposed Device	Predicate Device #1	Predicate Device #2	Differences
				raise new types of questions concerning safety and effectiveness, and the aiming beams are considered to be adequate for their intended purposes.

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

1) The V-Laser has been tested for conformance to the performance standards in the following table:

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's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 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			

- The patient-contacting materials of the proposed device′s handpiece are the same as those used for the K221427 device′s handpiece.

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

No clinical studies were considered to be necessary for this pre-market notification.

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

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, the proposed V-Laser device is considered to be substantially equivalent to the K221427 and K153671 devices.