WONTECH Co., Ltd.
Erin Park
Staff of Regulatory Affair
64 Techno 8-Ro, Yuseong-Gu
Daejeon, 305-500 KR

April 24, 2019

Re: K183156
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: November 9, 2018
Received: March 6, 2019

Dear Erin Park:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.04.24 14:51:18 -04'00'

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

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea, 305-500
Tel: +82-70-8730-8833 / Fax: +82-70-934-9491

005_Indications for Use Statement (FDA Form 3881)

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)*

K183156

Device Name
V-Lasaer

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea, 34028
Tel: +82-70-8730-8833 / Fax: +82-70-934-9491

510(k) Summary

[As Required by 21 CFR 807.92]

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

October 30, 2018

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

- Name of Sponsor: WON TECH Co., Ltd.
  - Address: 64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea, 305-500

- Contact Name: Erin Park / Staff of Regulatory Affair
  - Telephone No.: +82-70-8730-8833
  - Fax No.: +82-70-7836-3348
  - Email Address: loveyougyuri@wtlaser.com

- Name of Manufacturer: Same as sponsor
  - Address: Same as sponsor

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

Trade Name	V-Laser
Device Classification Name	Powered Laser Surgical Instrument
Regulation Number	21CFR878.4810
Classification Product Code	GEX
Device Class	Class II
510k Review Panel	General & Plastic Surgery

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea, 34028
Tel: +82-70-8730-8833 / Fax: +82-70-934-9491

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

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

Primary Predicate

- 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 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 Dynamic Cooling Device (DCD) protects the upper layers of the skin with a cooling burst of cryogen.

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.

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea, 34028
Tel: +82-70-8730-8833 / Fax: +82-70-934-9491

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

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the V-Laser and the predicate device:

	Proposed Device	Predicate Device
K Number	K183156	K153671
Manufacturer	WON TECH Co., Ltd.	Cutera, Inc.
Model	V-Laser	Family of CoolGlide Aesthetic Lasers
Product Code	GEX	GEX
Intended Use/ 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.	Excel V is Intended use is for surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.
Laser Type	Nd:YAG Laser	Nd:YAG Laser
Wavelength	1064 nm 532 nm	1064 nm 532 nm
Spot Size	1064 nm: 2 to 20 mm 532 nm: 2 to 20 mm Genesis Mode: 8 mm	1064 nm: 3 to 18 mm 532 nm: 2 to 12 mm Genesis Mode: 8 mm
Output	1064 nm: Max. 50 J 532 nm: Max. 10 J	1064 nm: Max. 100 J 532 nm: Max. 12 J
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
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
Repetition Rate	Max. 10 Hz	Max. 10 Hz
Laser Media	Flashlamp-pumped solid state rod	Flashlamp-pumped solid state rod
Aiming Beam	635 nm	630 to 680 nm
Dynamic Cooling Device (DCD)		
Cryogen	HFC 134a	Not applicable
DCD Spray Duration	10 to 100 ms	
DCD Delay Duration	Max. 100 ms	
DCD Post Spray Duration	0 to 20 ms	

The key differences between V-Laser and the predicate are (1) Spot Size and (2) Output, and which do not raise any new safety and effectiveness issues. The V-Laser and predicate device, K153671 have similar applicable fluence ranges, which are given in joules/cm^2.

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea, 34028
Tel: +82-70-8730-8833 / Fax: +82-70-934-9491

Verification and validation activities were conducted to establish the performance and safety characteristics of the V-Laser. The results of these activities show that there are no any new safety and effectiveness issues. Therefore, the V-Laser is considered substantially equivalent to the predicate.

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

1) Electrical Safety, Electromagnetic Compatibility and Performance

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:

Standards No.	Standards Organization	Standard Title	Version	Publication Year
ES60601-1	AAMI	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3.1	2012
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Edition 3	2007
60601-2-22	IEC	Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment	Edition 3.1	2012
60825-1	IEC	Safety of Laser Products - Part 1: Equipment Classification, and Requirements	Edition 3	2014

2) Software Validation

The V-Laser contains MODERATE level of concern software. The 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

According to the recommendations of ISO 10993-1 and FDA Blue Book Memo #G95-1, the following tests were performed:

- Cytotoxicity test according to ISO 10993-5:2009
- Intracutaneous (intradermal) reactivity test according to ISO 10993-10:2010
- Skin sensitization test according to ISO 10993-10:2010

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

No clinical studies were considered necessary and performed.

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea, 34028
Tel: +82-70-8730-8833 / Fax: +82-70-934-9491

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

Based on the information provided in this premarket notification WON TECH Co., Ltd., concludes that the V-Laser is substantially equivalent in safety and effectiveness to the predicate device.