DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 12, 2017

Won Tech Co., Ltd.
Mr. James Hoon Lim
Assistant Manager
64 Techno 8-Ro, Yuseong-gu
Daejeon, Republic of Korea 305-500

Re: K162755
Trade/Device Name: Picocare
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 17, 2017
Received: May 18, 2017

Dear Mr. Lim:

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" (21CFR 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 -S3

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)*
K162755

Device Name
Picocare

Indications for Use *(Describe)*
The Picocare is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.
1064 nm
The 1064 nm wavelength of the Picocare system is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI).
532 nm
The 532 nm wavelength of the Picocare system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

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.

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510(k) Summary

[As required by 21 CFR 807.92]

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

May 17, 2017

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
  - Telephone No.: +82-70-7805-1237
  - Fax No.: +82-70-7882-8658

- Contact Name: James Hoon Lim / Department Manager
  - Telephone No.: +82-10-3351-1414
  - Fax No.: +82-70-7882-8658
  - Email Address: drama@wtlaser.com

- Registration No.: 3006985208

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

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

Trade/Device Name	Picocare
Regulation Name	Powered Laser Surgical Instrument
Regulation Description	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Classification Panel	General & Plastic Surgery
Regulation Number	21 CFR 878.4810
Device Class	Class II
Product Code	GEX

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

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

Predicate Device

- 510(k) Number: K140727
- Applicant: Cutera, In
- Regulation Name: Powered Laser Surgical Instrument
- Trade/Device Name: enlighten Laser System

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

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

The Picocare is the solid state laser capable of delivering energy at wavelengths of 1,064 nm or 532 nm at short durations of 750 ps (picoseconds). The device system consists of a main unit, an articulated arm, a handpiece and a foot switch. The laser output is delivered to the skin through the articulated arm delivery system terminated by the handpiece. The fluence (energy density) and frequency 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.

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

The Picocare is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

1064 nm

The 1064 nm wavelength of the Picocare system is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI).

532 nm

The 532 nm wavelength of the Picocare system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

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7. Determination of Substantial Equivalence

The Picocare is substantially equivalent to the legally marketed predicate device with respect to technical feature comparison. The subject device was found to be similar to predicate device with regard to design, function, and technical characteristics. The table below presents comparisons for each device:

	Proposed Device		Predicate Device	
K Number	K162755		K140727	
Model	Picocare		enlighten Laser System	
Indications for Use	The Picocare is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. **1064 nm** The 1064 nm wavelength of the Picocare system is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI). **532 nm** The 532 nm wavelength of the Picocare system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.		The enlighten laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. **1064 nm** The 1064 nm wavelength of the enlighten laser system is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI). **532 nm** The 532 nm wavelength of the enlighten laser system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.	
Wavelength	1064 nm	532 nm	1064 nm	532 nm
Pulse Duration	750 ps	750 ps	750 ps or 2 ns	750 ps or 2 ns
Pulse Energy	(Max.) 600 mJ	(Max.) 300 mJ	(Max.) 600 mJ	(Max.) 300 mJ
Max Fluence	10 J/cm^2	2.5 J/cm^2	10 J/cm^2	2.5 J/cm^2
Delivery Element	Articulated Arm with Handpiece		Articulated Arm with Handpiece	
Spot Size	2 to 10 mm		2, 3, 4, 5, 6, or 8 mm	
Aiming Beam	635 nm		635 nm	
Repletion Rate	1 to 10 Hz		1 to 10 Hz	

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Justification to Support Substantial Equivalence
The Picocare laser has the same intended use as the predicate device with similar indications for use. It presents similar technological characteristics as the predicate device including the laser type, wavelengths, device design, pulse width, frequency, spot sizes and system components. The Picocare laser design and components are very similar to those of the predicate device. They all have treatment handpieces connected to the articulated arm that is connected to the main console where the user interface is located. They all allow the spot size to be adjusted with the handpiece depending on the application. They all provide an aiming beam to assist in delivery of the therapeutic energy Although there are some differences between the Picocare laser and its predicate device in terms of spot size, this difference does not present any new concerns of safety or effectiveness since the Picocare laser parameters are within the range used by the predicate device for treatment of tattoo removal. The Picocare laser and its predicate device operate with the same mechanism of action based on selective photothermolysis and based on photothermal and significant photomechanical or acoustic effects of pigments in tattoos. Therefore, the Picocare laser has the same intended use and similar indications for use, technological characteristics, and principles of operation as predicate device. Picocare laser is substantially equivalent to predicate devices.

Non-Clinical Test Summary:

1) Electrical Safety, Electromagnetic Compatibility:
   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 Date
60601-1	IEC	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	Third Edition 2005 + A1: 2012	January 17, 2012
60601-1-2	IEC	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility— Requirements and Tests	Third Edition	March 30, 2007
60601-2-22	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Third Edition	May 23, 2007
60825-1	IEC	Safety of laser products - Part 1: Equipment classification and requirements	Second Edition	March 30, 2007

2) Performance Test Report was also provided to the submission in order to support the characteristics of the subject device. Following performance testing were conducted to verify that the proposed device met all design specifications including pulse energy, pulse width, wavelength spectrum, beam profile, spot size, and repetition rate.

3) Software Validation

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

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

4) Biocompatibility

The biocompatibility evaluation of the all patient-contacting materials was demonstrated by the following testing:

- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: tests for irritation and skin sensitization

The test results demonstrated that the subject device is non-cytotoxic, non-irritating and non-skin sensitizing.

5) Cleaning Validation

The reprocessing instructions for reusable medical devices, Handpiece Tip and Protection Goggles are validated according to the FDA Guidance (Reprocessing Medical Devices in Health Settings: Validation Methods and Labeling issued on March 17, 2015). The User Manual of the Picocare provides the detailed, validated method of cleaning.

8. 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 Picocare is substantially equivalent to predicate devices as described herein.