July 22, 2020

WON TECH Co., Ltd.
Jake Yu
Staff of Regulatory Affairs
64 Techno 8-Ro, Yuseong-gu
Daejeon, 34028
Korea, Republic Of

Re: K201406
Trade/Device Name: Picowon
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 25, 2020
Received: May 28, 2020

Dear Jake Yu:

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 and Part 809); 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,

Colin Kejing Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201406

Device Name
Picowon

Indications for Use *(Describe)*
The Picowon is indicated for tattoo and benign pigmented lesions removal.

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)]

July 16, 2020

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, 34028

- Contact Name: Jake Yu/ Staff of Regulatory Affair
  - Telephone No.: +82-70-7836-6921
  - Fax No.: +82-70-934-9491
  - Email Address: regulatory@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	Picowon
Common Name	Powered Laser Surgical Instrument
Device Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810, Product Code GEX)
Regulation Number	21 CFR 878.4810
Classification Product Code	GEX
Device Class	Class II
510k Review Panel	General & Plastic Surgery

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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:

Primary Predicate device

- 510(k) Number: K121346
- Applicant: CYNOSURE, INC.
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR878.4810, Product Code GEX)
- Trade Name: Picosure™ workstation

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

The Picowon laser system is Alexandrite laser system. The Picowon laser system consists of an Alexandrite laser head, a power supply, a cooling system, a delivery system and other electrical components. The laser head contains Alexandrite laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed, in the special adjustable holders composed the laser cavity. And Picowon does not contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.).

The laser energies generated by the medium of Alexandrite is converted to the heat energy once it gets to human skin surface and used for tattoos and benign pigmented lesions removal. The combination of wavelength, pulse duration and energy fluence are disrupting the tattoo dye or pigment particles under the skin without harming the surrounding tissue. The fragmented dye or pigment particles eventually surface and fade as the epidermal layer or the skin is renewed. The system delivers laser energy at a wavelength of 755 nm. The output of the laser is delivered to the treatment area through an articulated Arm with a handpiece. A trigger (Foot Switch) controls the delivery of pulses. The user selects and sets the treatment parameters and other functions operated by software on the graphical user interface.

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

The Picowon is indicated for tattoo and benign pigmented lesions removal.

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 Picowon and the predicate device:

	Proposed Device	Predicate Device	SE decision
K Number	K201406	K121346	-

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	Proposed Device	Predicate Device	SE decision
Manufacturer	WON TECH Co., Ltd.	Cynosure, Inc.	-
Model	Picowon	Picosure™ workstation	-
Product Code	GEX	GEX	Same
Indications for Use	The Picowon is indicated for tattoo and benign pigmented lesions removal.	The Picosure™ workstation is indicated for tattoo and benign pigmented lesions removal.	Same
Laser Type	Flash lamp-excited, Solid state Alexandrite laser	Flash lamp-excited, Solid state Alexandrite laser	Same
Wavelength	755nm	755nm	Same
Maximum Average Fluence	6.37 J/cm^2	6.37 J/cm^2	Same
Pulse Duration	600-800 ps	450-900 ps	Similar, in the range of pulse duration of predicate device, more specific
Repetition Rate	1-5 Hz	1-10 Hz	Similar, less than predicate device, safer
Spot Size	Zoom 2, 3, 3.5, 4, 5, 5.5, 6, 7, 8 mm	Zoom 2-6 mm, Fixed 2,3,4,6,8,10 mm	Same

The pulse duration of Picocare is in the range of the pulse duration of predicate device. So the tissue reaction has no difference between them. And the repetition rate is related with only treatment time, but not effectiveness. Therefore the key differences between Picowon and the predicate device are Pulse duration and Repetition rate which do not raise any new safety and effectiveness issues. The Picowon and predicate device have the same wavelength, output power and indications for use.

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

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:

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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 4	2014
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	2012
60825-1	IEC	Safety of Laser Products - Part 1: Equipment Classification, and Requirements	Edition 3	2014

2) Software Validation

The Picowon 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

As an accessory, Picowon handpiece tip was designed not contacting to patient skin for the laser treatment effectiveness and aiming beam indicates a treatment laser radiation zone.

4) In-House performance test

In-House performance test for Picowon was conducted for verifying the accuracy of main performance specifications such as irradiation range (spot size), energy density, laser output accuracy, guide beam output limitation, laser output stability, operation check of the safety devices such as beam shutters, deviation of focal position of treatment guide light, variable range of pulse width and accuracy of repetitive frequency.

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

No clinical studies were considered necessary and performed.

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 Picowon is substantially equivalent in safety and effectiveness to the predicate device as described herein.