July 31, 2018

WON TECH Co., Ltd.
Erin Park
Regulatory Affair Staff
64 Techno 8-Ro, Yuseong-gu
Daejeon, 34028 KR

Re: K181272
Trade/Device Name: Picocare Family
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 20, 2018
Received: May 14, 2018

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,

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)*
K181272

Device Name
Picocare Family

Indications for Use *(Describe)*
The Picocare Family is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.
1064nm
The 1064nm wavelength of the Picocare Family 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).
532nm
The 532nm wavelength of the Picocare Family 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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10.510(k) Summary

510(k) Summary

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

19 June, 2018

10.2. 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 Person: Erin Park / Regulatory Affair Staff
  - Mobile Phone: +82-10-2776-0729
  - Email Address: loveyougyuri@wtlaser.com

- Submitter's Name: Yoon, Hyunsik / General Manager of Quality control Div.
  - Telephone No.: +82-10-6250-9299
  - Fax No.: +82-70-7882-8658
  - Email Address: yoonhs21@wtlaser.com

- Registration No.: 3006985208

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

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

- Trade Name: Picocare Family
- 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

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

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

4.1 Predicate Device1(Cleared Device)

- 510(k) Number: K162755
- Applicant: WON TECH Co., Ltd.
- Device Classification Name: Powered Laser Surgical Instrument
- Trade/Device Name: Picocare

4.2 Predicate Device2

- 510(k) Number: K153527
- Applicant: Syneron Candela Corporation
- Device Classification Name: Powered Laser Surgical Instrument
- Trade/Device Name: Picoway Laser System

There are no significant differences among the Picocare Family, the cleared device 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.

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

The Picocare Family is the solid state laser capable of delivering energy at wavelengths of 1,064 nm or 532 nm at short durations of 450 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.

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

The Picocare Family 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 Family 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 Family is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

10.7. Technological Characteristics

The modifications to the Picocare since its previous clearance in K162755 do not alter the safety or efficacy of the device. The predicate device produces pulse duration of 750 pico seconds. The modified Picocare Family utilizes the same laser out energy, including all other specifications such as, wavelength, spot size, Laser Class and Laser Delivery Type. The difference in the Picocare Family versus the Picocare(Cleared device)is the pulse duration. The Picocare Family produces 450 pico seconds and cleared Picocare produces 750 pico seconds. An adjustment in pulse duration of Picocare Family will be proved in safety and efficacy as the range of the duration is within the range of Picoway Laser System(K153527)'s pulse duration(240ps – 750ps). The indication of among devices is also the same with regard to 1064nm and 532nm wavelengths.

Therefore, the Picocare Family 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:

Device	Proposed Device	Predicate Device(Cleared Device)	Predicate Device 2
K Number	K162755	K162755	K153527
Model	Picocare Family	Picocare	Picoway Laser System
Indications for Use	The Picocare Family 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 Family 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 Family 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 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 PicoWay laser system is indicated for the following at the specified wavelength: **1064nm:** Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. **532nm:** Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

Substantial Equivalence

Picocare Family is as safe and effective as the predicate device, the Picocare, as well as the Picoway (K153527). The modified device has the same intended use of affecting Removal of tattoos as the predicate devices, as well as the same indications and the same specific indication of removal of tattoos in Fitzpatrick skin types I-III with 532nm and Fitzpatrick skin types I-VI with 1064nm. Safety profiles are the same: a laser module output within the limitation of a Class 4 laser (per IEC 60825-1), Q-Switched Nd:YAG Laser and the same laser Max Fluence (10J/cm2 at 1064nm and 2.5J/cm2 at 532nm) with Picocare, the spot size is exactly same as both Picocare and Picoway(2 to 10mm), and the repletion rate is the same as well.

WON TECH Co., Ltd. Special 510(k) Picocare Family has the same technological characteristics as the device cleared in K162755, including its laser class, laser power, wavelength, laser delivery method, device design, repletion rate, aiming beam, delivery element and pulse energy. The reduction in the pulse duration does not change the safety or effectiveness profiles. The modified Picocare Family device is also similar technologically to the Picoway Laser System and with pulse duration (450ps versus 240-750ps)

Non-Clinical Test Summary:

Design and development of the Picocare Family followed ANSI/AAMI/ISO 14971:2007/(R) 2010 Risk Management: Medical devices – Application of risk management to medical devices. WON TECH performed a Risk Analysis to evaluate the implications of the pulse duration changes to the Picocare. It was determined there was no significant change to risk and no new risks were identified with respect to the modifications to the Picocare Family. All residual risks were found to be acceptable. It was concluded the modified design could be tested in the laboratory and no animal or new clinical data was required to show safety, efficacy or substantial equivalence to the currently cleared model. Based on the Risk Analysis and modifications to the device, verification activities were conducted for the Picocare Family, including the same methods and tests using the same applied acceptance criteria as the previous Picocare. All the testing met acceptance criteria.

10.8. 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 Family is substantially equivalent to predicate devices as described herein.