January 7, 2022

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

Re: K212127
Trade/Device Name: Picocaremajesty
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: December 3, 2021
Received: December 10, 2021

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,

Purva Pandya
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)*
K212127

Device Name
PICOCAREMAJESTY

Indications for Use *(Describe)*

The PICOCAREMAJESTY Laser System 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 PICOCAREMAJESTY 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 PICOCAREMAJESTY 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.

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
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

K212127 510(k) Summary

[As required by 21 CFR 807.92]

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

January 7, 2022

2. Submitter 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: Nd:YAG Laser System
Trade name: PICOCAREMAJESTY

Classification Description	21 CFR Section	Product Code
Powered Laser Surgical Instrument	878.4810	GEX

As stated in 21 CFR, parts 878.4810, this generic types of devices has been classified as Class II.

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

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

- 510(k) Number: K181272
- Applicant: WON TECH Co., Ltd.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: Picocare Family

Predicate device

- 510(k) Number: K200166
- Applicant: Shanghai Apolo Medical Technology Co., Ltd.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: PicoSecond Nd: YAG Laser System

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

The PICOCAREMAJESTY is the solid state laser capable of delivering energy at wavelengths of 1064nm or 532nm at short durations. 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.

For treatment, the user can select the appropriate fluence value. The energy is changed automatically in accordance with the selected fluence (down) button and then, the fluence is increased / decreased by 0.1 J/cm^2.

The selectable fluence values are 0.2 to 16.0 J/cm^2. at 1064nm and 0.1 to 7.96 J/cm^2 at 532nm

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

The PICOCAREMAJESTY Laser System 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 PICOCAREMAJESTY 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 PICOCAREMAJESTY system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III

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

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

	Proposed Device	Predicate Device #1	Predicate Device #2	SE Decision
K Number	-	K181272	K200116	-
Manufacturer	WON TECH Co., Ltd.	WON TECH Co., Ltd.	Shanghai Apolo Medical Technology Co., Ltd.	-
Model	PICOCAREMAJESTY	Picocare Family	PicoSecond Nd: YAG Laser System	-
Indications for Use	The PICOCAREMAJESTY 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 PICOCAREMAJESTY 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)	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 PicoSecond Nd: YAG Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery as follows: 1064nm wavelength: ・Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following	Same

	Proposed Device	Predicate Device #1	Predicate Device #2	SE Decision
	532nm The 532nm wavelength of the PICOCAREMAJESTY system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III		tattoo colors: black, brown, green, blue and purple. • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV. 532nm wavelength: Removal of tattoos on Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange. • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.	
Anatomical site	Skin and subcutaneous tissue	Skin and subcutaneous tissue	Skin and subcutaneous tissue	Same
Principle/Method of Operation	The Main unit of PICOCAREMAJESTY is electrically to the facility power source. Laser energy produced by the Main Unit is delivered to the tissue through the articulated arm and handpiece. The footswitch is used to commence operation of the laser. The PICOCAREMAJESTY is operated with the software by controlling the main program. The software controls all the treatment parameters and	The Main Unit of Picocare Family is electrically connected to the facility power source. Laser energy produced by the Main Unit is delivered to the tissue through the articulated arm and handpiece. The Foot Switch is used to commence operation of the laser. The Picocare Family is operated with the software by controlling the main program. The software controls all the treatment parameters and extra functions to perform all treatment procedures.	The PicoSecond Nd: YAG Laser System produces a pulsed beam of coherent near infrared (1064nm) and visible (532nm) light. It can crush lesions tissue efficient by instantaneous emit laser energy, 1064 & 532nm wavelength act on the target tissue in a short time (300-500ps). The outputs of the two lasers are designed to be co-	Same

	Proposed Device		Predicate Device #1		Predicate Device #2		SE Decision
	extra functions to perform all treatment procedures.				linear on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 532 nm or 1064 nm wavelengths.		
Wavelength	1064 nm	532 nm	1064 nm	532 nm	1064 nm	532 nm	Same
Pulse Width	300 ~400 ps		450 ps		300 ~500 ps		Same with Predicate Device #2
Pulse Energy	500mJ	250mJ	600mJ(1064nm)	300mJ(532nm)	500mJ	250mJ	Same with Predicate Device #2
Spot Size	2 to 10 mm		2 to 10 mm		2 to 10 mm		Same
Pulse Repetition Rate	Max.10Hz		Max.10Hz		Max.10Hz		Same
Laser Delivery Type	Articulated Arm with Handpiece		Articulated Arm with Handpiece		Articulated Arm with Handpiece		Same
Handpiece	Zoom handpiece (532nm, 1064 nm)		Zoom handpiece (532nm, 1064 nm) and		Zoom handpiece (532nm, 1064 nm)		Same with Predicate Device #2
Patient Contact Material	Aluminum (Handpiece)		Aluminum (Handpiece)		Unknown		Same with Predicate Device #1

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

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

1) Electrical Safety, Electromagnetic Compatibility Testing

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:

Standard (Edition)	Standard Title
AASI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment
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 3.1 2012-10	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

2) Software Validation

The PICOCAREMAJESTY 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 guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

3) Biocompatibility

Part	Material	Patient Contact	Duration of Contact by ISO 10993-1	Bio-compatibility
Handpiece Tip of PICOCAREMAJESTY	Aluminium Powder (Cas No. 7429-90-5)	Intact Skin	Limited (< 24 hours)	Yes

- The material of handpiece for the PICOCAREMAJESTY is same to previous registered material of own product (PICOCARE Family <510k number: K181272>)

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

4) Performance Testing

The performance of the PICOCAREMAJESTY has been defined as follows.

- Laser wavelength: 1064nm ± 10%, 532nm ± 10%
- Laser output power: 1064nm mode: (30 to 500)mJ, 532nm mode: (20 to 250)mJ
- Pulse Width: 1064nm mode: 300-400 ps, 532nm mode : 300-400 ps
- Pulse repetition rate: 1064nm mode:1-10Hz, 532nm mode : 1-10Hz
- Radiation diameter: 1064nm mode: (2 to 10mm) step: 1mm,
  532nm mode: (2 to 10mm) step: 1mm

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

No clinical studies were considered necessary and performed.

10. 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 PICOCAREMAJESTY is substantially equivalent to predicate devices as described herein.