March 15, 2024

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

Re: K234104
Trade/Device Name: PICOANDY (Q-Switched Nd:YAG 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: December 22, 2023
Received: December 26, 2023

Dear Hyunsik 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2024.03.15
09:36:02 -04'00'

Tanisha Hithe
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)*
K234104

Device Name
PICOANDY (Q-Switched Nd:YAG Laser)

Indications for Use *(Describe)*
The PICOANDY is indicated for the following at the specified wavelength:
• 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.
• 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
• Treatment of benign pigmented lesions for Fitzpatrick skin types I-IV.

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)]

November 20, 2023

2. Submitter's 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: PICOANDY

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

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

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: K201773
- Applicant: Hironic Co., Ltd..
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: PICOHIGH

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

The PICOANDY 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.

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

The PICOANDY is indicated for the following at the specified wavelength:

• 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.

• 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

• Treatment of benign pigmented lesions for Fitzpatrick skin types I-IV.

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	SE Decision
K Number	-	K201773	-
Manufacturer	WON TECH Co., Ltd.	Hironic Co., Ltd	-
Model	PICOANDY	PICOHI	-
Indications for Use	The PICOANDY is indicated for the following at the specified wavelength: • 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. • 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the	The PICOHI is indicated for the following at the specified wavelength: • 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. • 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the	Same

	following tattoo colors: red, yellow and orange. • Treatment of benign pigmented lesions for Fitzpatrick skin types I-IV.		following tattoo colors: red, yellow and orange. • Treatment of benign pigmented lesions for Fitzpatrick skin types I-IV.		
Anatomical site	Skin and subcutaneous tissue		Skin and subcutaneous tissue		Same
Wavelength	1064 nm	532 nm	1064 nm	532 nm	Same
Pulse Width	350 ~550 ps		275~300ps		Similar However, pulse Width of the proposed device is higher than the predicate device, so proposed device is more safer
Pulse Energy	1. Zoom 1064nm : 30 ~ 550mJ ±10% 2. Zoom 532nm : 10 ~ 200mJ ±10% 3. Collimation Mode: 38 ~ 500mJ ±10% 4. MLA (1064nm): 30 ~ 550mJ ±10% 5. MLA (532nm): 10 ~ 200mJ ±10% 6. 1064nm DOE : 30 ~ 550mJ ±10% 7. 532nm DOE : 20 ~ 200mJ ±10%		1. Zoom 1064nm : 10 ~ 508mJ ±20% 2. Zoom 532nm : 4 ~ 255mJ ±20% 3. Collimation Mode: 7 ~ 471mJ ±20% 4. ZMLA (1064nm): 5 ~ 508mJ ±20% 5. ZMLA (532nm): 2 ~ 255mJ ±20% 6. 1064nm DOE : 10 ~ 500mJ ±20% 7. 532nm DOE : 10 ~ 250mJ ±20%		Similar The range of handpiece energy output used by Predicate devices is little or no different from the range of handpiece energy output used by proposed devices (including the +20% error range claimed by the proposed manufacturer)
Spot Size	2 to 10 mm(by 1mm step)		1.5-13 mm		Similar However, the range of the spot size of the proposed device is included in the range of the proposed device.
Pulse Repetition Rate	Max.10Hz		Max.10Hz		Same
Laser Delivery Type	Articulated Arm with Handpiece		Articulated Arm with Handpiece		Same
Handpiece	Zoom(1064nm, 532nm) Collimated(1064nm) MLA (1064nm, 532nm)		Zoom(1064nm, 532nm) Collimated(1064nm) VMLA (1064nm, 532nm)		Same

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	DOE (1064nm, 532nm)	ZMLA (1064nm, 532nm) DOE (1064nm, 532nm)	
Patient Contact Material	Aluminum powder (Handpiece)	Aluminum powder (Handpiece)	Same with Predicate Device #1

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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:

• IEC 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety

• IEC 60601-1-6 Edition 3.1 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance

• IEC 60601-2-22:2019 Medical electrical equipment –
Part 2-22: Particular requirements for basic safety and essential performance

• IEC 60825-1 Edition 3.0 2014 Safety of laser products - Part 1: Equipment classification, and requirements

• IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perform

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.

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3) Biocompatibility

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

- The material of handpiece for the PICOANDY is same to previous registered material of own product (PICOCARE Family <K181272>, and PICOCAREMAJESTY <K212127>))

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 600)mJ, 532nm mode: (10 to 200)mJ
- Pulse Width: 1064nm mode: 450-550 ps, 532nm mode : 350-400 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

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

No clinical studies were considered necessary and performed.

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 PICOANDY is substantially equivalent to predicate devices as described herein.