March 12, 2025

Wontech Co., Ltd.
Hyunsik Yoon
Regulatory Affairs Team General Manager
64 Techno 8-ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K243957
Trade/Device Name: Picoalex
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 23, 2024
Received: December 23, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.03.12 15:38:07 -04'00'

for 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K243957

Device Name
PICOALEX

Indications for Use *(Describe)*
PICOALEX is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma.

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:

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# 510(k) Summary (K243957)

[As required by 21 CFR 807.92]

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

March 4th, 2025

## 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 42 934 6800
- Fax No.: +82 42 934 9491
- Email Address: regulatory@wtlaser.com

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

Common name: Alexandrite Laser System
Trade name: PICOALEX

| Classification Description | 21 CFR Section | Product Code |
|---|---|---|
| Laser surgical instrument for use in general and plastic surgery and in dermatology | 878.4810 | GEX |

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

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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:

Predicate device 1

- 510(k) Number: K210226
- Applicant: Cynosure, LLC
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: PicoSure

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

The PICOALEX 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.

To provide energy to the flash lamp, high voltage power supply charges to a storage capacitor. Then, a trigger pulse applied to the flash lamps causes the capacitor to discharge through the flash lamps. The resulting flash excites the Alexandrite laser medium, causing the emission of a pulse of laser energy. Power supply and the laser resonator to the laser resonator is calculated from a power supply to the laser energy is set via the LCD monitor is a certain amount of power. In the laser resonator is a certain amount of electrical energy to the flash lamp by changing the electrical energy into light Alexandrite broiling to momentarily strong light in the laser medium to generate a laser. The generated laser is a laser return to convert heat energy reaches the surface tissue is cut by the heat energy, destruction, removal.

The electro-optic modulator with a polarizer introduced into the cavity creates the picoseconds pulse irradiation pulses. The sealed top metal cover protects all optical components from dust and humidity and blocks the visible and invisible scattering light from the laser head.

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.

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## 6. Statement of intended use [21 CFR 807.92(a)(5)]

PICOALEX is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma.

## 7. Summary of Technological Characteristics [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the PICOALEX 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 | - | K210226 | - |
| Manufacturer | WON TECH Co., Ltd. | Cynosure, LLC | - |
| Model | PICOALEX | PicoSure Work Station | - |
| Product Code | GEX | GEX | Same |
| Intended Use | PICOALEX is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma. | The PicoSure Workstation is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma. The PicoSure Workstation with the 2mm and 6mm hand pieces and the Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I – IV. | Similar as the intended use of the subject device is included in the intended use of the predciate |
| Principle/ Method of Operation | The PICOALEX 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. | The PicoSure Workstation is a high-powered, Alexandrite system that delivers laser energy in the 755-nm nominal wavelength. The system offers treatment through a variety of spot sizes, fluences and repetition rates. Laser activation is by footswitch. | Same |

| | | | |
|---|---|---|---|
| Laser Material | Alexandrite | Alexandrite | Same |
| Wavelength | 755nm | 1064nm, 532nm, 755nm | Same |
| Laser output power | Max 300mJ ± 20% | Max 300mJ ± 20% | Same |
| Repetition rate | 1-10 Hz | 1-10Hz | Same |
| Pulse width | 600-800ps | 450-900ps | Similar, as the range of the subject device is within that of predicate |
| Spot size | Zoom: 2-8mm ± 20%<br>MLA: 3.5-8mm ± 20% | Zoom: 2-6mm<br>Fixed: 6-10mm | Similar.<br>The differences do not raise problem in safety of the device because the larger the spot size, the more the energy of the laser disperse. |
| Maximum Average Fluence | 6.37J/cm$^2$ | 6.37J/cm$^2$ | Same |

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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 60601-2-22:2007/A:2012 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/A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perform

2) Software Validation

The PICOALEX 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 | Aluminium Powder (Cas No. 7429-90-5) | Intact Skin | Limited (< 24 hours) | Yes |

- The part of the device that comes into contact with the human body is the handpiece tip

4) Performance Testing

The performance of the PICOALEX has been defined as follows.

- Laser wavelength: 755nm
- Laser output power: Max 300mJ± 20%
- Pulse width: 600-800ps
- Pulse repetition rate: 1-10Hz

**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 PICOALEX is substantially equivalent to predicate devices as described herein.