June 28, 2024

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

Re: K241406
Trade/Device Name: Lavieen
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 14, 2024
Received: May 17, 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.

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
Digitally signed by TANISHA L. HITHE -S
Date: 2024.06.28 11:01:14 -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241406

Device Name

Lavieen

Indications for Use *(Describe)*

Lavieen is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

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.

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510(k) Summary
(K241406)

[As required by 21 CFR 807.92]

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

June 25th, 2024

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: Tm-doped fiver Laser System
Trade name: Lavieen

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.

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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: K223727
- Applicant: WON TECH Co., Ltd
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: Lavieen

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

Lavieen is a thulium laser, producing a pulsed beam of coherent near-infrared light (1927 nm) upon activation by a footswitch. The beam is then directed to the treatment zone by means of an optical fiber coupled to a handpiece. An integrated LED touch screen gives the user control over the necessary laser system parameters. Lavieen is equipped with a 658 nm aiming beam.

There are some modifications from the subject device to the predicate device.

Modifications are;

1. The Circuit Breaker is exposed at the behind of the device.
2. The new fiber holder and handpiece pouch is added.
3. The shape of the Top Case
4. New Laser module is added. The manufacturer will select from 2 modules.

Max powers of two modules are different, with 10W and 15W. However, the max power of the Lavieen is 10W, the max power of the laser module will be controlled by the software, so that both modules will finally have the same max power of 10W.

The software validation is also submitted for the eSTAR submission.

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

Lavieen System is indicated for dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

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

There are no significant differences between Lavieen 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	-	K223727	-
Manufacturer	WON TECH Co., Ltd.	WON TECH Co., Ltd.	-
Model	Lavieen	Lavieen	-
Intended Use	Lavieen is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).	Lavieen is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).	Same
Laser Type	Thulium laser	Thulium laser	Same
Laser Wavelength	1927 nm	1927 nm	Same
Aiming Beam	658 nm	658 nm	Same
Beam Delivery	Fiber and Handpiece	Fiber and Handpiece	Same
Emission Control	Foot Switch	Foot Switch	Same
Laser Power	10W	10W	Same
Pulse Duration	0.1 – 20 ms	0.1 – 20 ms	Same
Pulse Repetition Rate	67 – 240 Hz	67 – 240 Hz	Same
Spot Size	300 ㎛	300 ㎛	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:

Standard (Edition)	Standard Title
IEC 60601-1:2005, AMD2:2020	Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 , AMD1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-22:2019	Medical electrical equipment – Part 2-22: Particular requirements for Basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

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2) Software Validation

Lavieen contains Basic Documentation Level 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: Content of premarket submissions for Device Software Functions, on November 04, 2021.

3) Biocompatibility

Part	Material	Patient Contact	Duration of Contact by ISO 10993-1	Bio-compatibility
Handpiece Tip	ABS	Intact Skin	Limited (< 24 hours)	Yes

4) Performance Testing

The performance of Lavieen has been defined as follows.

- Max output power: 10 W

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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 Lavieen is substantially equivalent to the predicate device as described herein.