August 25, 2023

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

Re: K223727
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: August 3, 2023
Received: August 3, 2023

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,

Tanisha L. Hithe -S

Digitally signed by Tanisha L. Hithe -S
Date: 2023.08.25 09:37:31 -04'00'

Tanisha Hithe, MS, MHS
Assistant Director
DHT4A: General Surgery Devices
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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)*
K223727

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.

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K223727 510(k) Summary

[As required by 21 CFR 807.92]

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

December 12, 2022

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: K171009
- Applicant: Lutronic Corporation
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: LASEMD Laser System

Predicate device #2

- 510(k) Number: K182173
- Applicant: Sciton, Inc
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: Joule System

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.

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	Predicate Device #2	SE Decision
K Number	-	K171009	K182173	-
Manufacturer	WON TECH Co., Ltd.	Lutronic Corporation	Sciton, Inc	-
Model	Lavieen	LASEMD Laser System	Joule System	-
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).	The LASEMD Laser 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).	The JOULE 1927nm Laser System with its accessories 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).	Same
Laser Type	Thulium laser	Thulium laser	Thulium laser	Same
Laser Wavelength	1927 nm	1927 nm	1927 nm	Same
Aiming Beam	658 nm	658 nm	658 nm	Same
Beam Delivery	Fiber and Handpiece	Fiber and Handpiece	Articulated Arm or Fiber optic	Same
Emission Control	Foot Switch	Foot Switch	Foot Switch	Same
Laser Power	10W	5W	12W	Same
Pulse Duration	0.1 – 20 ms	Max 20 ms	Max 20 ms	Same
Pulse Repetition Rate	67 – 240 Hz	43.5 – 307.7 Hz	0 – 3,000 Hz	Same
Spot Size	300 ㎛	100 ㎛, 200 ㎛	100 – 620 ㎛	Same to predicate device #2

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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, AMD1:2012	Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	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 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 Edition 2.0:2007-03	Safety of laser products – Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1(2008), Interpretation Sheet 1(2007), Interpretation Sheet 2(2007)]

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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 predicate devices as described herein.