January 21, 2025

WON TECH Co., Ltd.
Hyun Sik Yoon
General Manager
64 Techno8-ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K243929
Trade/Device Name: Oligio X
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 18, 2024
Received: December 20, 2024

Dear Hyun Sik 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2025.01.21 11:19:32 -05'00'

Long Chen, Ph.D.
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)*

K243929

Device Name

Oligio X

Indications for Use *(Describe)*

The 'Oligio X' is intended for use in dermatologic and general surgical procedures for non-invasive electrocoagulation and hemostasis of soft tissue.

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

[As required by 21 CFR 807.92]

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

2024.12.20

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: Radio Frequency Therapy System
Trade name: Oligio X

Classification Description	21 CFR Section	Product Code
Electrosurgical Cutting and Coagulation Device and Accessories	878.4400	GEI

As stated in 21 CFR, parts 878.4400, 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

- 510(k) Number: K240313
- Applicant: WON TECH Co., Ltd.
- Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Trade Name: Oligio X

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

Oligio X is a radio frequency therapy system. The radio frequency output of the device is 6.78 MHz, and the maximum power is 200 W. Oligio X consists of a main body including touch LCD monitor, a RF handpiece, return pads, a return pad cable, non-sterile treatment tips, cooling gas, coupling fluids, footswitch and a power cable.

Oligio X RF System delivers radio frequency energy for selective coagulation of tissue while conductively cooling the epidermis. Oligio X delivers energy form the disposable tip to the patient, and employs radio frequency turning to provide radio frequency energy across a range of impedances for delivery to the patient through the tip.

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

Oligio X is intended for use in dermatologic and general surgical procedures for non-invasive electrocoagulation and hemostasis of soft tissue.

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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 Oligio X 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	SE Decision
K Number	-	K240313	-
Manufacturer	WON TECH Co., Ltd.	WON TECH Co., Ltd	-
Model	Oligio X	The Olgio	-
Intended Use	Dermatologic and general surgical procedures for non-invasive electrocoagulation and hemostasis of soft tissue	Dermatologic and general surgical procedures for non-invasive electrocoagulation and hemostasis of soft tissue	Same
Anatomical site	Skin and soft tissue	Skin and soft tissue	Same
Principle/Method of Operation	'Oligio X' RF System delivers radio frequency energy for selective coagulation of tissue while conductively cooling the epidermis. 'Oligio X' delivers energy form the disposable tip to the patient, and employs radio frequency turning to provide radio frequency energy across a range of impedances for delivery to the patient through the tip.	'Oligio X' RF System delivers radio frequency energy for selective coagulation of tissue while conductively cooling the epidermis. 'Oligio X' delivers energy form the disposable tip to the patient, and employs radio frequency turning to provide radio frequency energy across a range of impedances for delivery to the patient through the tip.	Same
Output frequency	6.78MHz ± 1%	6.78MHz ± 1%	Same
Max output power	140 W	145 W	Different The Device Max output power has been changed into 140 W, due to the marketing strategy of the manufacturer.
Dimension of RF tip	0.25, 4.0 cm^2	0.25, 4.0 cm^2	Same
Mode of Operation	Manual or footswitch	Manual or footswitch	Same
Dimensions (Main body)	479 ㎜(W) x 490 ㎜(D)	580 ㎜(W) x 490 ㎜(D)	Different

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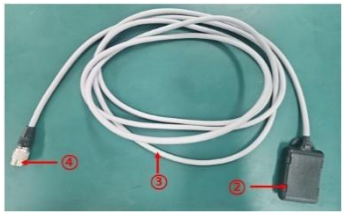
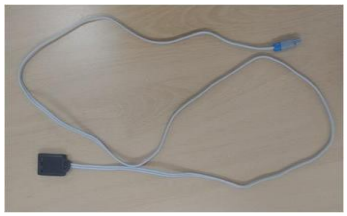
	x 1210 ㎜(H)	x 1210 ㎜(H)	The Dimensions has been changed into 479mm width, due to the marketing strategy of the manufacturer.
Appearance of Main Unit			Different The Return pad has been changed into back position and Foot Switch cable connection position has been added, due to the marketing strategy of the manufacturer.
Accessories of Return Cable	 Size: 3.0m	 Size: 1.7m	Different The Return Cable has been changed into longer, due to the marketing strategy of the manufacturer.
Accessories of Foot Switch		-	Different The Foot Switch has been added new, due to the marketing strategy of the manufacturer.

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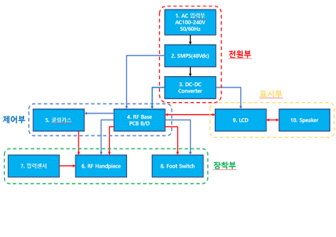
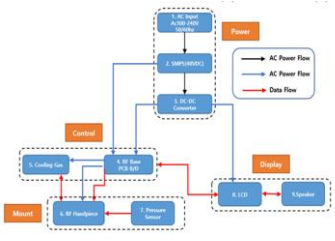
Accessories of Cooling gas	 (R-134a) (R-1234ZE)	 (R-134a)	Different The Cooling gas has been added new, due to the marketing strategy of the manufacturer.
Accessories of Coupling fluid			Different The Coupling fluid has been changed tube design, due to the marketing strategy of the manufacturer.
GUI Design			Different The GUI has been changed, due to the marketing strategy of the manufacturer.
Electrical Design - SystemBlockDiagram			Different The SystemBlockDiagram has been changed, due to the marketing strategy of the manufacturer.

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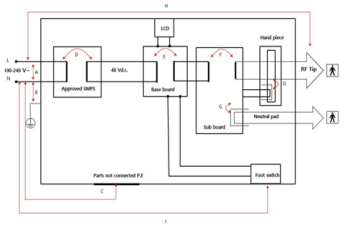
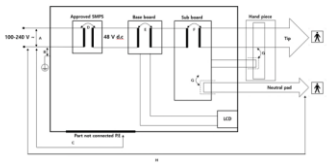
Electrical Design - InsulationDiagram			Different The InsulationDiagram has been changed, due to the marketing strategy of the manufacturer.

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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 60601-2-2:2017 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
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 61000-3-2:2018	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)

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2) Software Validation

Oligio X 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**
RF tip	Polyethylene terephthalate	Intact Skin	Limited (< 24 hours)	Yes

4) Performance Testing

The performance of Oligio X has been defined as follows.

- RF output frequency: 6.78MHz ± 1%
- Max output power: 140 W
- Handpiece vibration: Low (30dB), Medium (40dB), High (50dB)

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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 Oligio X is substantially equivalent to predicate devices as described herein.