10/13/2022

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

Re: K221989
Trade/Device Name: The Oligio
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 13, 2022
Received: October 13, 2022

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,

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221989

Device Name
The Oligio

Indications for Use *(Describe)*

'The Oligio' is intended for use in dermatologic and general surgical procedures for 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.

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510(k) Summary

[As required by 21 CFR 807.92]

K221989

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

September 13, 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: Radio Frequency Therapy System
Trade name: The Oligio

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: K170758
- Applicant: Solta Medical Inc.
- Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Trade Name: Thermage FLX System

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

'The Oligio' is a radio frequency therapy system. The radio frequency output of the device is 6.78 MHz, and the maximum power is 145 W. 'The Oligio' 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 and a power cable.

'The Oligio' RF System delivers radio frequency energy for selective coagulation of tissue while conductively cooling the epidermis. 'The Oligio' 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)]

'The Oligio' is intended for use in dermatologic and general surgical procedures for 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 The Oligio 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	K221989	K170758	-
Manufacturer	WON TECH Co., Ltd.	Solta Medical Inc.	-
Model	The Oligio	Thermage FLX System	-
Intended Use	Dermatologic and general surgical procedures for electrocoagulation and hemostasis of soft tissue.	Dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Same
Principle/Method of Operation	'The Oligio' RF System delivers radio frequency energy for selective coagulation of tissue while conductively cooling the epidermis. 'The Oligio' 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.	The Thermage FLX System delivers RF energy for selective coagulation of tissue while conductively cooling the epidermis. The Thermage FLX System delivers energy from the disposable tip to the patient. The System and its Handpiece monitor skin contact during treatment. The System employs RF tuning to provide RF energy across a range of impedances for delivery to the patient through single and multiple pass stamping motions of the tip.	Same
Output frequency	6.78MHz ± 1%	6.78MHz	Same
Max output power	145 W	400 W	Different
Different – Max output power The Max output power for proposed device is different from the predicate devices. However, the Max output power of the proposed The Oligio is covered by the range of the Max output power of the predicate device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.			
Mode of Operation	Manual or footswitch	Manual or footswitch	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, 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

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

4) Performance Testing

The performance of The Oligio has been defined as follows.

- RF output frequency: 6.78MHz ± 1%
- Max output power: 145 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 The Oligio is substantially equivalent to predicate devices as described herein.