March 21, 2023

Chungwoo CO., LTD.
% Milly (RA Consultant/KMC,Inc.
DongHa Lee (RA Consultant / KMC, Inc.
KMC, Inc.
(G-Plus Tower, # 1709) 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

Re: K222709
Trade/Device Name: Retraction, CWM-910T, APOLEX Tite
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 7, 2022
Received: September 8, 2022

Dear Milly (RA Consultant/KMC, Inc.):

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.03.21 13:21:10 -04'00'

Mark Trumbore, 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)*
K222709

Device Name
Retraction, CWM-910T, APOLEX Tite

Indications for Use *(Describe)*
For use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

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.

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510(k) Summary (K222709)

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 7, 2022

1. Applicant / Submitter

CHUNGWOO CO., LTD

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2. Official Correspondent (RA Consultant)

Milly (RA Consultant / KMC, Inc.)

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3. Device Information

- Trade Name: Retraction, CWM-910T, APOLEX Tite
- Common Name: RF Electrosurgical System
- Classification Name: Electrosurgical cutting and coagulation device and accessories
- Classification Product Code and Regulation: GEI, 21CFR 878.4400
- Device Class: 2

4. Predicate Device

- K Number: K173582
- Manufacturer: ThermiGen, L.L.C.
- Trade Name: ThermiX Temperature Controlled Radiofrequency (RF) System

5. General Description

Retraction, CWM-910T and APOLEX Tite are RF electrosurgical system. These are identical except for model designation.

The RF electrosurgical system consists of an electrosurgical device (ESU), 3 types of detachable handpieces (mono-polar active electrode), a grounding plate (neutral electrode) and a foot switch.

The hand piece consists of a hand grip and an electrode. There are 3types of mono-polar electrode depend on diameter and length.

The electrosurgical device generates 480KHz RF current. RF output energy (Max. 50W) is delivered

through a mono-polar active electrode and returned through the grounding plate (neutral electrode).

6. Indication for use

For use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

7. Comparison of the modified device to the cleared device

The following comparison table is presented to demonstrate substantial equivalence.

Descriptive Information		Subject Device	Predicate Device	Comparison
Manufacturer		CHUNGWOO CO., LTD.	ThermiGen, L.L.C.	-
Device Name		RF electrosurgical System (Models: Retraction, CWM-910T, APOLEX Tite)	ThermiX Temperature Controlled Radiofrequency (RF) System	-
510(k) number		-	K173582	-
Regulatory Number		21CFR 878.4400	21CFR 878.4400	Same
Classification Product Code		GEI	GEI	Same
Regulatory Class		2	2	Same
Indications for Use		For use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	- for use in dermatological and general surgical procedures for electrocoagulation and hemostasis - to create lesions in nervous tissue	Same (Note. 1)
Prescription or OTC		Prescription	Prescription	Same
Operation		Radio frequency (RF) alternating current to heat the tissue by RF induced intracellular oscillation of ionized molecules that result in an elevation of intracellular temperature.	Radio frequency (RF) alternating current to heat the tissue by RF induced intracellular oscillation of ionized molecules that result in an elevation of intracellular temperature.	Same
Electrosurgical Unit (ESU)	Monopolar or Bipolar	Monopolar	Monopolar	Same
	Temperature sensors	Yes	Yes	Same
	Impedance monitor	Yes	Yes	Same
	Continuity monitor	Yes	Yes	Same

	Output frequency	480kHz	460kHz	Similar (Note. 2)
	Waveform	Sine curve	Sine curve	Same
	Max. Output Power	50W	50W	Same
	Voltage output	140Vrms	140Vrms	Same
	Power Input	AC 100-240V, 50/60Hz, 190-200VA	AC 100-240V, 50/60Hz, 190VA	Similar (Note. 3)
Active accessory (RF Electrode)	Monopolar or Bipolar	Monopolar	Monopolar	Same
	Physical Dimensions	AE20-80 (LIFT) 1) Diameter: Ø 2.0 2) Length: 80mm	V-10-10-18-B-G2 1) Diameter: Ø 1.15 2) Length: 100mm	Different (Note. 4)
		AE20-180 (SMART) 1) Diameter: Ø 2.0 2) Length: 180mm	V-15-10-18-B-G2 V-20-10-16-B-G2 V-5-5-20-B-G2 1) Diameter: Unknown 2) Length: Unknown	
		AE40-300 (LIPO) 1) Diameter: Ø 4.0 2) Length: 300mm		
	Raw Materials	SUS304 (Insulation coating: TEFLON-PFA)	Unknown	Different (Note. 5)
	Single Use or Reusable	Reusable	Reusable	Same
	Sterilization	User Sterilization (Steam sterilization)	Unknown	Different (Note. 6)
Grounding Plate - Neutral electrode pad	FDA Approval	K092761 (PROPLATE Electrosurgical Grounding Plate)	Unknown	Different (Note. 7)
	Single Use or Reusable	Single Use	Single Use	Same
	Specifications	Plug the grounding pad cord into the connection port of ESU. Attach the grounding pad on the patient during the procedure.	Plug the grounding pad cord into the connection port of ESU. Attach the grounding pad on the patient during the procedure.	Same
Miscellaneous accessory (Foot switch)	Functions	Start or stop RF power delivery	Start or stop RF power delivery	Same
	Performance Specifications	Press and release the footswitch	Press and release the footswitch	Same
	Specification	IP68	Unknown	Different (Note. 8)

Note 1.

The indications for use of the subject device is included within The indications for use of the predicate device.

Note 2.

RF output power and waveform of the subject device is the same as the predicate device. Output frequency of the subject device is 480 kHz which is similar to the predicate device (460kHz). The RF output was tested and verified according to IEC 60601-2-2 and performance bench testing (comparison test).

Note 3.

Power input of the subject device is similar to the predicate device. The electrical safety was tested and verified according to IEC 60601-1 and IEC 60601-1-2. EMC also was tested and verified according to IEC 60601-1-2.

Note 4.

The shape of the RF electrode of the subject device is similar to the predicate device but dimension (diameter and length) is little bit different. The difference was tested and verified according to IEC 60601-2-2 and performance bench testing (comparison test).

Note 5.

Raw material of the patient contact part (RF electrode) is different from the predicate device.

The patient contact part (RF electrode) of the subject device was evaluated about bio-compatibility according to ISO 10993-1. Bio-compatibility was tested and verified according to ISO 10993-5, ISO 10993-10, ISO 10993-11 and ISO 10993-23.

Note 6.

The reprocessing method of the reusable handpiece (hand grip and electrode) of the subject device is different from the predicate device. The reprocessing method was tested and validated according to FDA reprocessing guidance.

Note 7.

The grounding plate (neutral electrode pad) of the subject device is different from the predicate device. The grounding plate (neutral electrode pad) of the subject device is FDA cleared product (K092761). The compatibility with the subject device was tested and verified according to IEC 60601-2-2.

Note 8.

The footswitch of the subject device is different from the predicate device. The footswitch was tested and verified according to IEC 60601-1 with the subject device.

8. Reprocessing

The reusable hand piece (hand grip and electrode) should be conducted reprocessing after use to prevent contamination and cross-infection.

The reprocessing method was tested and validated according to FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff”.

9. Biocompatibility

The RF electrode can be touched with a patient. Biocompatibility tests were conducted to ensure that no risks arise from biological hazards associated with materials of manufacture and the final device.

1) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
3) ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
4) ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation

10. Software

The firmware is intended to control the RF electrosurgical system. It is installed in a microprocessor of the device.

The firmware was verified and validated according to FDA Guidance "Content of Premarket Submission for Software Contained in Medical Devices" and IEC 62304: 2006 + A1:2015, Medical device software - Software life cycle processes.

11. Electrical Safety and Electromagnetic compatibility

Electrical hazard and high temperature hazard are included within the device. The risks are controlled by design, protection method and information according to the FDA recognized standards, IEC 60601-1:2005+A1:2012 (AAMI/ANSI ES 60601-1: 2005+A1: 2012) and IEC 60601-2-2:2017

Electromagnetic compatibility was tested and verified according to the FDA recognized standard, IEC 60601-1-2:2020

12. Performance Testing – Bench

The RF output power was tested and verified according to with the FDA recognized standard, IEC 60601- 2-2:2017.

Comparison Test with the predicate device was conducted about graphical display of the output waveform at the rated load, identifying the associated mode, amplitude, frequency, duty cycle, load used, and crest factor. This test also considered a graph displaying the power output at maximum and half-of-maximum intensity over the range of expected loads (100/200/500/1000/2000 Ω). These tests are according to FDA guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery: Guidance for Industry and Food and Drug Administration Staff".

In addition, as part of comparison test, animal (mini pig) test was conducted to assess the safety assessment (thermal effect) between subject device and predicate device. The skin, liver, kidney, and femoral muscles dissected from 9 mini pigs were used in the thermal tissue spread experiments.

Thermal imaging area analysis, maximum temperature and time to reach basal temperature were evaluated. the subject device showed a tendency to decrease in maximum temperature by all set temperatures compared to the predicate device. And the subject device did not show any change in the time reaching basal temperature by all set temperatures compared to the predicate device. The

results of thermal imaging area analysis using the correction factor, considering that it is two - four folds larger than the predicate device, the thermal image area of the subject device showed a tendency to decrease in thermal image area compared to the predicate device.

13. Conclusion

The major consideration such as intended use and principle of operation is the same as the predicate device. Although there are some differences, the safety and performance test reports are supported to the safety and effectiveness of the subject device.

In this regard, we conclude that the subject device is substantially equivalent to the predicate devices.