September 2, 2022

RF Medical Co., Ltd
% Dave Kim
Regulatory Affairs
Mtech Group
7505 Fannin St, Suite 610
Houston, Texas 77054

Re: K221277
Trade/Device Name: Mygen M-3004 RF Generator M-3004
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 22, 2022
Received: May 3, 2022

Dear Dave Kim:

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)*
K221277

Device Name
Mygen™ M-3004 RF System

Indications for Use *(Describe)*

The Mygen M-3004 RF system is intended for use in percutaneous and intraoperative coagulation and ablation of 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.

510(k) Summary
K221277

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

I. SUBMITTER

Submitter's Name :	RF Medical Co Ltd.
Submitter's HQ Address:	#502~#507,#511, #601 254, Beotkkot-ro Geumcheon-gu Seoul Korea
Submitter's Telephone:	+82-2-2108-4200
Contact person:	Kwang S. Choi (ra@rfa.co.kr) / RD Manager
Official Correspondent:	Dave Kim (davekim@mtech-inc.net)
Address:	7505 Fannin St. Suite 610, Houston, TX 77054
Telephone:	+713-467-2607

SUBJECT DEVICE

Trade/proprietary name:	Mygen™ M-3004 RF System
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Regulatory Class:	Class II

Prescription Use.

PREDICATE DEVICE

Primary Device Manufacturer:	RF Medical Co., Ltd
Device Name:	Mygen V-1000 RF System
510(k) Number:	K180999
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI)
Regulatory Class:	Class II

1st REFERENCE DEVICE

Primary Device Manufacturer:	STARmed Co., Ltd
Device Name:	VIVA Combo RF System
510(k) Number:	K163450
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI)
Regulatory Class:	Class II

2nd REFERENCE DEVICE

Primary Device Manufacturer:	Covidien LLC
Device Name:	Cool-tip RF Ablation System
510(k) Number:	K203150
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI)
Regulatory Class:	Class II

This predicate has not been subject to a design-related recall.

II. DEVICE DESCRIPTION

Mygen M-3004 RF System consists of a microprocessor based RF generator, a cooling pump and tubing, electrodes, and ground pads. The generator, pump and electrodes are designed to produce local tissue heating at the tip of the electrodes causing the coagulation (ablation) of the tissue. Mygen M-3004 RF System generator is capable of delivering up to 200 waits (into a 50 Ohm resistive load) while monitoring tissue impedance and electrode tip temperature during the delivery of the RF energy. The generator includes manual and impedance control and displays/monitors impedance, current, power and temperature.

The radiofrequency (RF) energy, which is delivered to an electrode, makes frictional heat for coagulation and ablation on diseased tissue by ionic agitation. The patient can receive safe therapy as leakage current is extremely low. Mygen M-3004 continually measures and displays RF output power, tissue impedance, and elapsed time of RF delivery. Tissue temperature is measured by the thermocouple embedded in the electrode tip and is displayed on the touch screen. This equipment automatically adjusts the output to maximize the delivery of high-frequency energy and displays the measured temperature from the treatment site during high-frequency emission.

Mygen M-3004 automatically adjusts the output to optimize radiofrequency output and displays the measured temperature from the treatment area while delivering radiofrequency energy.

III. INDICATIONS FOR USE:

The Mygen M-3004 RF system is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed device	Predicate device	Remark
Model name	M-3004 RF system	Mygen V-1000 RF system (K180999)	
Manufacturer	RF Medical Co., Ltd	RF Medical Co., Ltd	
	The M-3004 RF system is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	The Mygen V-1000 RF system is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	Same
Type of Use	Prescription Use	Prescription Use	Same
Components	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	Same
Electrosurgical RF applicator	Monopolar bipolar	Monopolar	SE
Output energy type	High frequency	High frequency	Same
Operation mode	Manual mode / Auto mode	Manual mode / Auto mode	Same
User interface	Color Touch Panel	Color Touch Panel	Same
Electrical Requirements	110VC, 50/60Hz, 410VA	110VAC, 50/60Hz, 300VA	SE
Output Frequency	480kHz ± 10%	400kHz ± 10%	Same
Max power	Max 200W @ 50Ω	Max 140W @ 50Ω	SE
Power of per electrode pin	Max 200W	Max 140W	SE
Power density	Max 200 W/㎠	Max 140 W/㎠	SE
Treatment time	Up to 30min	12 min , Up to 30 min	SE
Electrode Length (mm)	60,70,100,150,200,250,300, 350	70, 100	SE
Exposure Tip Length (mm)	5, 10, 15, 20, 25, 30, 35, 40	5, 10,15. 20	SE

	Proposed device	Predicate device	Remark
Intensity	0~240W (1W step)	0 ~ 140W (1W step)	SE
Sterile	EO Sterilization	EO Sterilization	Same
Single Use	Single Use	Single Use	Same

1st Reference Device

	Proposed device	**Reference device**	**Remark**
Model name	M-3004 RF system	VIVA COMBO RF SYSTEM (K163450)	
Manufacturer	RF MEDICAL CO.,LTD	STARmed Co., Ltd.	
	The M-3004 RF system is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	The VIVA combo RF Ablation System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	Same
Electrosurgical RF applicator	Monopolar / Bipolar elelctrode	Monopolar Applicator	Similar
Output energy type	High frequency	High Frequency	Same
Delivery system	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	Same
Output Frequency	480 kHz ± 10 %	480 kHz ± 10 %	Same
Electrode Length (mm)	60,70,100,150,200,250,300,350	70, 150, 200	Similar
Exposure Tip Length (mm)	5, 10, 15, 20, 25, 30, 35, 40	5, 10, 15, 20, 25, 30	Similar
RF Duration	Up to 30 minutes	Up to 30 minutes	Same
Maximum Power Output	Up to 200 watts @ 50 Ω	Up to 200 watts @ 50 Ω	Same

2nd Reference Device

	Proposed device	**Reference device**	**Remark**
Model name	M-3004 RF system	Cool-tip RF Ablation System (K203150)	
Manufacturer	RF MEDICAL CO.,LTD	Covidien LLC	
	The M-3004 RF system is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	The Cool-tip RF Ablation System E Series (generator, pump, patient return electrodes, water container, active electrodes, footswitch, and accessories) is intended for use in percutaneous, laparoscopic, and intraoperative coagulation	Same

	Proposed device	Reference device	Remark
		and ablation of tissue, including partial or complete ablation of non-resectable liver tumors.	
Output energy type	High frequency	High Frequency	Same
Delivery system	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	Same
Electrode Length (mm)	60,70,100,150,200,250,300,350	100, 150, 200, 250	Similar
Exposure Tip Length (mm)	5, 10, 15, 20, 25, 30, 35, 40	7, 10, 20, 25, 30, 40	Similar
Maximum Power Output	Up to 200 watts @ 50 Ω	Up to 200 watts @ 50 Ω	Same

V. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

In order to verify the device performance, the worst case was selected from each of the 4 types of electrodes included in the subject device. BIG-TIP(BTM3540QB) / JET-TIP®(JET3540XB) / VARY-TIP™(VCTU20XXB) / THYBLATE™(RFTP10XXHLN)

Worst case was selected based on the high energy transfer rates: diameter thickness, long exposure, and longest needle length for each type.

A total of 6 performance comparison tests were conducted with the selected 4 types of handpieces and the performance outcome was verified through CSA group's testing lab.

- Test List -

① Accuracy of output
② Accuracy of energy transfer
③ Active electrode resistor
④ High frequency and mains frequency dielectric strength of active electrode
⑤ Accuracy of tip temperature
⑥ High frequency leakage of active electrode

Biocompatibility testing:

The patient contact components and materials are tested and validated according to ISO10993-1;2009

Biocompatibility
Cytotoxicity study using MEM elution assay in L929 cells found that the extract from the test subject is non-cytotoxic
Guinea Pig Maximization Test for Delayed Hypersensitivity result shows that the test subject is a non-sensitizer and non-allergenic material to the guinea pigs.
Intracutaneous Reactivity Test result shows that the test subject is considered as a non-skin irritant, since the difference between the test extract and control score is less than 1 in both physiological saline and vegetable oil.
Pyrogen Testing in New Zealand White Rabbits shows that the test subject is free of material mediated pyrogens and does not exhibit pyrogenicity potential in New Zealand White Rabbits
Acute Systemic Toxicity test result shows that the test subject is not toxic to the ICR mice after single intravenous injection at a dose level of 20 mL/kg.
LAL Validation and quantitative LAL test item showed endotoxin levels less than 0.0500 EU/device. Therefore, the requirement (endotoxin level < 20 EU/device) outlined as endotoxin tolerance limit K has been fulfilled for the tested device.

Non Clinical testing:

IEC 60601-1 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance. The requirements of specified standards were fulfilled.

IEC 60601-1-2 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance (collateral standards: electromagnetic compatibility.

IEC 60601-2-2: 2017 Medical electrical equipment

Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Sterilization and Shelf Life

The active electrode of Mygen M-3004 RF system is delivered in a sterile state and is intended for single use only. The sterilization method used is ethylene oxide and this device has a shelf life of 3 years**.**

The requirements of sterilization testing standards including ISO 10993-7: 2008, ASTM F1929-15: 2015, and ASTM F88/F88M-15: 2015 were fulfilled.

Animal testing :

In vivo animal testing using micropig models was also conducted with Mygen M-3004 RF system to obtain histological data of values for depth and zone of ablation and thermal damage immediately post treatment; 7 days post treatment; and 14 days post treatment.

The treatment was performed at the intensity(power) 10W, 60W, 120W, 200W and depth of needling 3mm, 5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm.

VI. CONCLUSIONS

There are no significant differences between Mygen M-3004 RF system, the subject device, and Mygen V-1000, the predicate device. The proposed device does not raise any questions regarding safety and effectiveness. Mygen M-3004 RF system has the same indication of use as the predicate device. All systems share the same technological characteristics.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, it is the opinion of RF Medical Co, Ltd. that Mygen M-3004 RF system is substantially equivalent in comparison with the predicate device and the reference devices.