August 3, 2020

RF Medical Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
MTech Group
7707 Fannin St. Ste 200, V111
Houston, Texas 77054

Re: K193355/S002
Trade/Device Name: Electrode Handpieces (BT, JET)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, JOS
Dated: July 13, 2020
Received: July 16, 2020

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 and Part 809); 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193355

Device Name
Electrodes Handpieces (BT, JET)

Indications for Use *(Describe)*

Electrodes Handpieces (BT, JET) are indicated for coagulation and ablation of soft tissue when used in conjunction with Mygen V-1000 radio frequency generator.

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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Special 510(k) Summary
K193355

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

Date 510k summary prepared: 7/30/2020

I. SUBMITTER

Submitter's Name :	RF Medical Co., Ltd.
Submitter's HQ Address:	#502, 503, 505, 506, 507,511, 254, Beotkkot-ro, Geumcheon-gu, Seoul, KOREA,
Submitter's Telephone:	+82-2-2108-4200
Contact person:	Kwang S Choi (ra@rfa.co.kr) / RA Manager
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Telephone:	+713-467-2607

DEVICE

Trade/proprietary name:	Electrode Handpieces (BT, JET)
Common Name:	Electrosurgical Cutting and Coagulation Accessories
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, JOS
Regulatory Class:	Class II

Prescription Use.

PREDICATE DEVICE (K180999)

Primary Device Manufacturer:	RF Medical Co. Ltd
Trade/proprietary name:	Electrodes Handpieces for Mygen V-1000 RF System
Model:	RFT
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, JOS
Regulatory Class:	Class II

REFERENCE DEVICE (K181249)

Device Manufacturer:	STARmed Co., Ltd
Device Name:	EUSRA RF Electrode
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, JOS
Regulatory Class:	Class II

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

II. DEVICE DESCRIPTION

Electrodes Handpieces (BT, JET) are sterile, single-use electrosurgical electordes intended to be use in conjunction with Mygen V-1000 RF generator (K180999).

Electrodes Handpieces (BT, JET) consist of electrode tip, insulation part, handle.
Cooling of the electrode is provided by saline which is pumped (using the peristaltic pump) through the inflow tubing, the electrode and out through the outflow tubing. This is an enclosed system within the electrode and saline does not contact the patient. For the electrodes (BT, JET), dispersive electrodes are provided so that electrical current flows through the tip of the electrodes, through the target tissue and to the dispersive electrodes.

III. INDICATIONS FOR USE:

Electrodes Handpieces (BT, JET) are indicated for coagulation and ablation of soft tissue when used in conjunction with Mygen V-1000 radio frequency generator.

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed device	Predicate device	Remark
Model name	Mygen V-1000 RF System Electrodes Handpieces (BT, JET)	Mygen V-1000 RF System Electrodes Handpieces (RFT)	
Manufacturer	RF Medical Co., Ltd	RF Medical Co., Ltd	
	Electrodes Handpieces (BT, JET) are indicated for coagulation and ablation of soft tissue when used in conjunction with Mygen V-1000 radio frequency generator.	The Mygen V-1000 RF system is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	SE
Type of Use	Prescription Use	Prescription Use	
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	Monopolar	Same
Output energy type	Radio frequency	Radio Frequency	Same
Electrode Length (mm)	100 ~ 200 mm	70mm, 100 mm	SE
Exposure Tip Length (mm)	5, 10, 15, 20, 25, 30 mm	5, 10, 15, 20 mm	SE
Patient contacting materials	SUS 304, Polymer, Polyester, Polyimide	SUS 304, Polymer, Polyester, Polyimide	SE
Sterile	EO Sterilization	EO Sterilization	Same
Single Use	Single Use	Single Use	Same

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE

	Proposed device	Reference device	Remark
Model name	Electrodes Handpieces (BT, JET)	EUSRA RF Electrode K181249	
Manufacturer	RF Medical Co., Ltd	STARmed Co., Ltd	
	Electrodes Handpieces (BT, JET) are indicated for coagulation and ablation of soft tissue when used in conjunction with Mygen V-1000 radio frequency generator.	The EUSRA RF Electrode is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.	SE
Type of Use	Prescription Use	Prescription Use	
Components	Electrosurgical unit, active electrode, grounding pad,	Electrosurgical unit, active electrode, grounding pad,	Same

	Proposed device	Reference device	Remark
	peristaltic pump and foot pedal	peristaltic pump and foot pedal	
Electrosurgical RF applicator	Monopolar	Monopolar	Same
Output energy type	Radio frequency	Radio Frequency	Same
Operation mode	Manual mode / Auto mode	Manual mode/ Automatic impedance control	Same
Electrode Length (mm)	100 ~ 200 mm	70mm, 200 mm	SE
Exposure Tip Length (mm)	5, 10, 15, 20, 25, 30	5, 7, 10, 15, 20 mm	SE
Patient contacting materials	SUS 304, Polymer, Polyester, Polyimide	Stainless Steel 304, Polyimide, Polyether Block Polyamide Copolymer, Stainless Steel 304 and PTFE	SE
Sterile	EO Sterilization	EO Sterilization	Same
Single Use	Single Use	Single Use	Same

VI. SUMMARY OF TECHNOLOGICAL COMPARISON BETWEEN THE SUBJECT AND PREDICATE DEVICE

The indications for use, operating principle, technical specifications of the subject device described in this 510k are identical to those of the predicate device, RFT electrode for Mygen V-1000 RF System.

The differences include the length of the tip of the electrodes and the size of the handpieces.

VII. PERFORMANCE DATA

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

Biocompatibility testing:

The patient contact components and materials are tested and validated according to ISO10993-1;2009. They are identical to the predicate device.

Shelf-Life testing

Electrodes Handpieces (BT, JET) are sterilized and tested for packaging seal strength, packaging dye penetration, appearance, conduction, and sterility in accordance with ASTM F 1980 Accelerated Aging method for valid shelf life. All testing results passed the

acceptance criteria.

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: 2009 Medical electrical equipment

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

The requirements of specified standards were fulfilled.

Temperature sensor accuracy test of RF electro-surgical cautery apparatus (V-1000) was performed to test and verify the accuracy of the temperature sensor of the equipment produced by RF Medical . Temperature accuracy was tested in multiple power mode, three times for each power setting. The test results confirmed that the values measured by temperature sensor of V-1000 and the temp. calibrator were within the acceptance criteria, ±3°

LAL Validation and Quantitative

LAL test for the electrode material has been conducted according to the United Sates Pharmacopoeia (USP) [3] [4] in the guidance by the Food and Drug Administration and the ANSI/AAMI. (ULMDT Endotoxicological laboratory, Project 12280140 1.1, Orcle No: 4788458245).

Bacterial endotoxin concentration was less than 0.050 EU/device and the acceptance criteria for the validity of the test were fulfilled.

There were no deviations from the study protocol.

A thermal effect test

Electrodes Handpieces (BT, JET) have been tested for a thermal effect according to the FDA guidance 'Premarket Notification (510K) Submission for Electrosurgical Devices for General Surgery'. The test was conducted on a pig' liver, kidney and muscle tissue, during immediately after treatment to verify the safety and effect it will have on the tissue and surrounding anatomical structures. Parameters of necrosis cross-sectional aera show

coagulated necrotic cells with markedly collapsed cellular architecture. By comparison, the surrounding liver, thyroid, muscle tissues were normal in appearance.

No clinical studies were considered for this submission.

VIII. CONCLUSIONS

Electrodes Handpieces (BT, JET) have the same indication of use as the predicate devices and it shares the same technological characteristics as the predicate devices.
There is no new concern for safety and effectiveness.

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 Electrodes Handpieces (BT, JET) are substantially equivalent in comparison with RFT electrode for Mygen V-1000 RF System, the predicate device as described herein.