



October 4, 2023

RF Medical Co., Ltd  
% Mr. Dave Kim, MBA  
President  
Mtech Group LLC  
7505 Fannin St. Suite 610  
Houston, Texas 77054

Re: K232763

Trade/Device Name: Electrode Handpieces (VCT, RFTV, BMDT)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: August 22, 2023

Received: September 8, 2023

Dear Mr. 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 (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.

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](mailto: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: 2023.10.04  
08:09:32 -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

## Indications for Use

510(k) Number (if known)

K232763

Device Name

Electrodes Handpieces (VCT, RFTV, BMDT)

Indications for Use (Describe)

Electrodes Handpieces (VCT, RFTV, BMDT) are indicated for coagulation and ablation of tissue when used in conjunction with Mygen V-1000 RF generator (K193355) and M-3004 RF generator (K221277).

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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## **Special 510(k) Summary K232763**

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

**Date of Submission: 10/3/2023**

### **I. SUBMITTER**

|                         |                                                                                   |
|-------------------------|-----------------------------------------------------------------------------------|
| Submitter's Name :      | RF Medical Co., Ltd.                                                              |
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| Submitter's Telephone:  | +82-2-2108-4200                                                                   |
| Contact person:         | Kwang S Choi ( ra@rfa.co.kr ) / RA Manager                                        |
| Official Correspondent: | Dave Kim, MBA<br>President                                                        |
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### **DEVICE**

|                         |                                                             |
|-------------------------|-------------------------------------------------------------|
| Trade/proprietary name: | Electrode Handpieces (VCT, RFTV, BMDT series)               |
| 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 (K193355)**

Primary Device Manufacturer: RF Medical Co. Ltd  
Trade/proprietary name: Electrodes Handpieces for Mygen V-1000 RF System  
Model: BT, JET  
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 (VCT, RFTV, BMDT) are sterile, single-use electrosurgical electrodes intended to be used in conjunction with a compatible radio frequency generator, mainly Mygen V-1000 RF generator (K193355) and M-3004 RF generator (K221277).

Electrodes Handpieces (VCT, RFTV, BMDT) 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 (VCT, RFTV, BMDT), 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 (VCT, RFTV, BMDT) are indicated for coagulation and ablation of tissue when used in conjunction with compatible radio frequency generators, Mygen V-1000 RF generator (K193355) and M-3004 RF generator (K221277).

**IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

|              | Proposed device                                       | Primary Predicate Device                          | Remark |
|--------------|-------------------------------------------------------|---------------------------------------------------|--------|
| Model name   | Electrodes Handpieces (VCT, RFTV, BMDT), K232763      | Electrodes handpieces (BT, JET), K193355          |        |
| Manufacturer | RF Medical Co., Ltd                                   | RF Medical Co., Ltd                               |        |
|              | Electrodes Handpieces (VCT, RFTV, BMDT) are indicated | Electrodes Handpieces (BT, JET) are indicated for | SE     |

|                               | Proposed device                                                                                                                             | Primary Predicate Device                                                                                     | Remark |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------|
|                               | for coagulation and ablation of tissue when used in conjunction with Mygen V-1000 RF generator (K193355) and M-3004 RF generator (K221277). | coagulation and ablation of soft tissue when used in conjunction with Mygen V-1000 radio frequency generator |        |
| 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)         | 60 ~ 300 mm                                                                                                                                 | 60 ~ 300 mm                                                                                                  | SE     |
| Exposure Tip Length(mm):      | 5, 10, 15, 20, 25, 30 mm                                                                                                                    | 5, 10, 15, 20, 25, 30 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. 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, BT, JET electrode for V-1000 and M-3004 RF generator system.

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

## VI. 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: 2018. They are identical to the predicate device.

### **Shelf-Life testing**

Electrodes Handpieces (VCT, RFTV, BMDT) 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: 2005, AMD 1: 2012 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: 2014 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.

The requirements of specified standards were fulfilled.

Temperature sensor accuracy test of RF electro-surgical cautery apparatus (VCT, RFTV, BMDT series) 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,  $\pm 3^{\circ}$

### **LAL Validation and Quantitative**

LAL test for the electrode material has been conducted according to the United States Pharmacopoeia (USP) [3] [4] in the guidance by the Food and Drug Administration and the ANSI/AAMI. (ULMDT Endotoxological 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 (VCT, RFTV, BMDT series) 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's 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 area 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.

## **VII. CONCLUSIONS**

Electrodes Handpieces (VCT, RFTV, BMDT series) 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 (VCT, RFTV, BMDT series) are substantially equivalent in comparison with BT, JET electrode, the predicate device as described herein.