December 26, 2024

Bomtech Electronics Co., Ltd.
℅ Juntaek Seo
President
Corazon
20, Jukjeon-ro, Giheung-gu, Gyeonggi-do
Yongin, 16897
Korea, South

RE: K243097
Trade/Device Name: RM STAR EX with RMS Needle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 30, 2024
Received: September 30, 2024

Dear Seo Juntaek:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Francisco Delgado -S
11:42:22 2024.12.26
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243097

Device Name
RM STAR EX with RMS Needle

Indications for Use *(Describe)*
The RM STAR EX with RMS Needle is intended for use in dermatologic 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.

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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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

510(k) Submitter: BOMTECH ELECTRONICS CO., LTD.
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Phone: +82 2 523 8295

Primary Contact: Juntaek Seo
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Alternate Contact: Junseok Lee
RA manager
bomtech@bomtech.net

Date Prepared: December 23, 2024

II. Device Name

Device Trade Name: RM STAR EX with RMS Needle

Common Name: Electrosurgical cutting and coagulation device and accessories

Regulation Number: 21 CFR 878.4400

Product Code: GEI

Regulatory Class: Class II

Classification Panel: General and Plastic Surgery

III. Legally Marketed Predicate Device

Predicate #: K213612

Predicate Trade Name: SYLFIRM X

IV. Device Description

The RM STAR EX with RMS Needle includes a system main device and a handpiece equitable with a bipolar electrode. The RF signal is generated from the main device which is then delivered to the handpiece and then to bipolar electrode. The RF signal is delivered to the target tissue using penetrating needle electrodes in the consumable tip. The bipolar electrode is placed in light contact with the epidermis while the handpiece

is being held at right angles to the target tissue. As the RF signal passes through the skin, it generates an electrothermal reaction which is capable of coagulating the tissue. Using the consumable tip, RM STAR EX with RMS Needle creates heat within the target skin tissue via needle electrodes from the bipolar electrode.

The model names and numbers of the products applied for are as follows:

Model Numbers	Model Name	
	Main Body + Handpiece	RMS Needle
1	RM STAR EX	RMS-13P31G
2		RMS-13P32G
3		RMS-13P33G

V. Indications for Use

The RM STAR EX with RMS Needle is intended for use in dermatologic procedures for electrocoagulation and hemostasis.

VI. Comparison of technological characteristics with the predicate device

The RM STAR EX with RMS Needle is substantially equivalent to the following predicate device:

Primary Predicate: For Indication for Use and Technological Characteristics

- K213612, Sylfirm X

Item		RM STAR EX	SYLFIRM X	Remark
510(k) Number		K243097	K213612	-
Manufacturer		Bomtech Electronics Co., Ltd.	VIOL Co., Ltd.	-
Regulation Number No.		21 CFR 878.4400	21 CFR 878.4400	Same
Product Code		GEI	GEI	Same
Indications for Use		The RM STAR EX with RMS Needle is intended for use in dermatologic procedures for electrocoagulation and hemostasis.	The SYLFIRM X is intended for use in dermatologic procedures for electrocoagulation and hemostasis.	Same
Prescription or OTC		Prescription	Prescription	Same
ESU	General	RM STAR EX is a bipolar electrosurgical device for tissue coagulation using high-frequency RF current.	SYLFIRM X is a bipolar electrosurgical device for tissue coagulation using high-frequency RF current.	Same
	Major functions	• Operation type: Coagulation	• Operation type: Coagulation	Same

<table>
<tr><th colspan="2">Item</th><th>RM STAR EX</th><th>SYLFIRM X</th><th>Remark</th></tr>
<tr><td rowspan="2"></td><td>Performance specifications</td><td>• Output power: Max 16 W (50 Ω)
• Conduction time
<table><tr><th>Mode</th><th>Conduction time</th></tr><tr><td>Level 1</td><td>100 msec</td></tr><tr><td>Level 2</td><td>120 msec</td></tr><tr><td>Level 3</td><td>160 msec</td></tr><tr><td>Level 4</td><td>200 msec</td></tr><tr><td>Level 5</td><td>Continuous</td></tr></table>• Output frequency: 2 MHz</td><td>• Output power: Max 16 W (50 Ω)
• Conduction time
<table><tr><th>Mode</th><th>Conduction time</th></tr><tr><td>CW1</td><td>120 msec</td></tr><tr><td>CW2</td><td>160 msec</td></tr><tr><td>CW3</td><td>200 msec</td></tr><tr><td>CW4</td><td>300 msec</td></tr><tr><td>PW1</td><td>120 msec</td></tr><tr><td>PW2</td><td>160 msec</td></tr><tr><td>PW3</td><td>200 msec</td></tr><tr><td>PW4</td><td>240 msec</td></tr></table>• Output frequency: 2 MHz</td><td>Similar (Note 1)</td></tr>
<tr><td>Physical specifications</td><td>• Input voltage: AC 100 - 240 V, 50/60 Hz</td><td>• Input voltage: AC 100 - 240 V, 50/60 Hz</td><td>Same</td></tr>
<tr><td rowspan="5">Active accessory</td><td>Monopolar or bipolar</td><td>Bipolar</td><td>Bipolar</td><td>Same</td></tr>
<tr><td>Physical specifications</td><td>• Depth: 0 - 2.0 mm (unit: 0.5 mm)</td><td>• Depth: 0.3 - 4.0 mm (unit: 0.1 mm)</td><td>Similar (Note 2)</td></tr>
<tr><td>Disposable</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Consumable tip</td><td>Provided</td><td>Provided</td><td>Same</td></tr>
<tr><td>Number of electrodes</td><td><table><tr><td>RMS-13P31G</td><td>RMS-13P32G</td><td>RMS-13P33G</td></tr><tr><td>13-pin</td><td>13-pin</td><td>13-pin</td></tr></table></td><td><table><tr><td>J25BM</td><td>J25BS</td><td>J18BS</td></tr><tr><td>25-pin (5x5)</td><td>25-pin (5x5)</td><td>18-pin (3x6)</td></tr></table></td><td>Similar (Note 3)</td></tr>
<tr><td>Biocompatibility</td><td>This is satisfied with biocompatibility according to ISO 10993.</td><td>This is satisfied with biocompatibility according to ISO 10993.</td><td>Same</td></tr>
<tr><td colspan="2">Neutral electrodes</td><td>Not applicable</td><td>Not applicable</td><td>Same</td></tr>
</table>

<u>Note 1</u>: Conduction time

The conduction time of the subject device is 100 msec to 200 msec and continuous.
The conduction time of the predicate device is 120 msec to 300 msec.
These differences in conduction time do not raise different questions of safety and effectiveness because conduction time of the subject device is shorter than that of the predicate device.
The safety and effectiveness of the subject device was supported by animal test (Doc. No. NT24-00035, NT24-00036).

<u>Note 2</u>: Depth

The depth of the subject device is 0 to 2.0 mm.
The depth of the predicate device is 0.3 to 4.0 mm.
These differences in depth do not raise different questions of safety and effectiveness because depth of the subject device is not greater than that of the predicate device.
The safety and effectiveness of the subject device was supported by animal test (Doc. No. NT24-00035, NT24-00036).

<u>Note 3</u>: Number of electrodes

The number of electrodes of the subject device is 13 pins.
The number of electrodes of the predicate device is 25 pins.

These differences in number of electrodes do not raise different questions of safety and effectiveness because the number of electrodes of the subject device is fewer than that of the predicate device.
The safety and effectiveness of the subject device was supported by animal test (Doc. No. NT24-00035, NT24-00036).

Based on the above comparison as well as the information provided in the SE Comparison Table in Section VI, supported by the appropriate performance data, the proposed device has been shown to be as safe and effective as the legally marketed predicate device for the proposed Indications for Use.

VII. Performance data

1. Biocompatibility Testing

In accordance with ISO 10993-1, the subject device is classified as an externally communicating device in contact with tissue/bone/dentin for limited duration (< 24 hours). The following testing was conducted.

1) Cytotoxicity
2) Sensitization
3) Irritation
4) Acute Systemic Toxicity
5) Material-Mediated Pyrogenicity

2. Sterilization Validation Test

To confirm a sterility assurance level of 10^{-6} for EO sterilization, the validation process employed the biological indicator (BI) overkill method, following the guidelines outlined in ISO 11135, ISO 10993-1, ISO 10993-7, ISO 11138-1, ISO 11138-2, ISO 11737-1, ISO 11737-2, ISO 11140-1, AAMI TIR 15, AAAMI TIR 16, and AAMI TIR 28.

3. Shipping, Packaging, and Shelf Life

- Pyrogen test was conducted in accordance with USP <161> Medical Devices - Bacterial Endotoxin and Pyrogen Tests and USP <85> Bacterial Endotoxins Test.

- Package integrity testing, after environmental conditioning and simulated transportation using ASTM D4169-22, was conducted on final packaged and sterile devices. All packaging is acceptable for protection of final finished product and sterility maintenance.

- Sterile Barrier Packaging Testing was performed on the proposed device:
    - Seal peel test – ASTM F88/F88M-15

- Dye penetration - ASTM F1929-15

- Shelf life of 3 years is validated using the FDA-recognized standard ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Devices.

4. Electrical Safety and EMC Test

The subject device has been evaluated for electrical safety and electromagnetic compatibility in accordance with the relevant standards, including IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014/A1:2020, IEC 60601-2-2:2017/AMD1:2023, IEC TR 60601-4-2:2016, EN 55011:2016 + A1:2017 (CISPR 11:2015/A1:2016), and IEC 61000-3-2:2018/AMD1:2020.

5. Software Validation Test

The level of concern of the software of RM STAR EX with RMS Needle is moderate, and the software validation tests were performed.

6. Pre-clinical Test

The RM STAR EX with RMS Needle was evaluated for safety and effectiveness through comprehensive pre-clinical testing using both internal organs and skin models.

1) Study Design
Radiofrequency (RF) microneedling was applied to liver, kidney, and muscle as well as the skin of rabbits to assess the localized effects of RF energy. The animals were euthanized at different time points (3 hours, 5 days, and 22 days post-treatment) to observe tissue response and healing.

2) Tissue Reactions
In the internal organ models, minimal hemorrhage and fibrosis were observed, with no significant gross lesions at any time point. In the skin model, mild dermal necrosis was observed shortly after treatment, but the tissue exhibited good recovery, with minimal fibrosis noted by Day 22.

3) Histological Findings
Histopathological analysis showed that the tissue damage was localized and well-controlled, with signs of tissue healing and regeneration over time. No major adverse reactions were observed in either the skin or internal organs.

4) Conclusion
The RM STAR EX with RMS Needle demonstrated controlled tissue interaction with no adverse effects and effective healing in both skin and internal organ models, confirming the safety and effectiveness of the device.

VIII. Conclusion

Based on the test results provided in this submission, including biocompatibility, sterilization validation, shipping, shelf life, EMC and electrical safety, software validation, and animal testing, Bomtech Electronics Co., Ltd. concludes that the RM STAR EX with RMS Needle is substantially equivalent to the predicate device as described herein.