January 30, 2024

STARmed Co., Ltd.
% Bobae Jung
General Manager
JNM Korea
#207, #206 Building, Gunpo IT Valley
17, Gosan-ro 148beon-gil
Gunpo-si, 15850
Korea, South

Re: K234140
Trade/Device Name: VIVA combo RF System (VIVA combo RF System)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 27, 2023
Received: December 29, 2023

Dear Bobae Jung:

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

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.01.30 07:55:47 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

VIVA combo RF System (VIVA combo RF System)

Indications for Use *(Describe)*

The VIVA combo 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.

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

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

1. Date Prepared

27/12/2023

2. Submitter's Information

Name of Sponsor:	STARmed Co., Ltd.
Address:	B-dong, 4F&12F, 158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si, Gyeonggi-do, Republic of Korea
Contact Name:	Honggeun Lee Telephone #: +82-10-2363-4998 Fax #: +82-31-816-4546 Email: lhg1186@starmed4u.com
Registration Number:	3013557681
Name of Manufacturer:	STARmed Co., Ltd.

3. Device information

Trade Name:	VIVA combo RF System
Common Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Ⅱ

4. Predicate Device

VIVA combo RF System, Electrosurgical Cutting and Coagulation Device and Accessories, K183538

5. Purpose to submission

This special 510(k) pre-market notification is submitted for using a tablet with a UI for user, which allows user to view information in real time on interacting tablet monitor which used STAR Logger software as predicate device software K183538.

6. Description of the Device

The VIVA combo RF System consists of RF generator, active electrode, grounding pad and peristaltic pump for electrode cooling. This device is designed to produce local tissue heating at the tip of the electrodes causing the coagulation and ablation of tissue. VIVA combo RF System is capable of delivering up to 200 W of RF power and the available power is limited through software control. This system monitors the power, resistance, current and temperature.

The active electrodes are a sterile, single-use, hand-held electrosurgical instrument designed for use with VIVA combo RF System. Cooling of the electrode is provided by chilled water which is pumped through the inflow tubing, the electrode and out through the outflow tubing. This is an enclosed system within the electrode and the water is not to be in contact with the patient.

VIVA combo RF System consists of S_VCS_F, MRFALogger and STAR Logger.
The S_VCS_F software continuously monitors impedance, current, power and temperature. The unit automatically monitors rises in impedance and adjust RF output accordingly.
MRFALogger software can be stored and monitored on PC or tablet the RF output parameter (power, impedance, current, temperature and energy).
STAR Logger can be stored and monitored on a tablet PC the RF output parameter (power, impedance, current, temperature and energy).

7. Indications for Use

The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.

8. Technological Characteristics

No changes have been made to the technological characteristics of the device.

9. Comparison to the Predicate Device

The modified device has no design changes comparing with previous one.
But replaced software VIVA Logger software with STAR Logger for using tablet with device.

Software architecture changes: The purpose of STAR Logger is to provide convenience for the user by displaying certain data that is also shown on the VIVA combo RF Generator. The VIVA combo RF generator communicates with the software via a USB communication cable or RS232 to USB converter using serial communication.

Software: replaced VIVA Logger software with STAR Logger.

10. Summary of Non-Clinical Testing

Software verification and validation was conducted on the changed to VIVA combo RF System software to validate it for its intended use per the design documentation in line with recommendations outlined in General Principles of Software Validation, Guidance for Industry and FDA staff. The VIVA combo RF System demonstrated passing results on all applicable testing.

Risk assessment and safety of the replaced STAR Logger was evaluated for compliance to the following FDA -Recognized Consensus Standards:

- ANSI AAMI ISO 14971: 2019- Medical devices - Application of risk management to medical devices
- IEC 62304: 2006 [AMD1:2015]- Medical device software – Software life cycle processes
- IEC TIR80002-1:2009 - Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software

11. Summary of Clinical test

No clinical studies were considered necessary and performed.

12. Conclusion

The subject device(VIVA combo RF System) and its predicate have the same indication and principle of operation, and identical technological characteristics. The minor difference in the newer device version is to using replaced software STAR Logger with tablet PC which do not present different questions of safety or effectiveness as compared to the predicate device. Verification testing according to the company's design control procedures demonstrates that the subject device is as safe and effective as its predicate device. Thus, the subject device is substantially equivalent to its predicate device.