January 17, 2019

STARmed Co., Ltd.
Mr. Jun-Young Jung
QMR/ Deputy General Manager
B-dong, 4F&12F, 158, Haneulmaeul-ro, IlsanDong-gu
Goyang-si, Gyeonggi-do,10355, Republic of Korea

Re: K183538
Trade/Device Name: 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 10, 2018
Received: December 19, 2018

Dear Mr. 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.01.17 14:18:53 -05'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

K183538

Device Name

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.

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510(k) Summary

[As required by 21 CFR 807.92]

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

1. Date Prepared [21 CFR 807.92(a) (1)]

12/10/2018

2. Submitter's Information [21 CFR 807.92(a) (1)]

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:	Mr. Jun-Young Jung Telephone #: +82-70-4673-8657 Fax #: +82-31-816-4546 Email: jjy3412@starmed4u.com Job Title : QMR/Deputy General Manager Degree : Bachelor's degree in Business(BBA)
Registration Number:	3013557681
Name of Manufacturer:	Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

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

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

510(k) Number:	K163450
Applicant:	STARmed Co., Ltd.
Model Name:	VIVA combo RF System
Common Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Device Class:	II

5. Description of the Modified Device [21 CFR 807.92(a) (4)]

<Modification>

- VIVA Combo RF System
  - Apply an isolation of USB PCB and Foot Switch PCB using DC-DC Converter and Digital Isolators
  - Change a foot switch connector type and a data communication connector type
    : The connector type has been changed from male type to female type.
  - Addition of accessories (hospital-grade power cable)
  - Change a fuse from T 5AL 250 V to F 5AH 250 V

- Software
  - S_VCS_F Software for VIVA Combo RF System
    : Version Change (1.10 to 1.11F) – In the temperature mode, RF current is cut-off at 15 ohms (previous version: cut off at 25 ohms)
  - MRFALogger for PC
    : Version Change (1.10 to 1.41) - Interface Change (No functional changes)
  - VIVALogger for Tablet PC
    : Version Change (2.20 to 3.30) − Support different screen size (No functional changes)

- VIVA Pump
  - Change a SMPS board from ECS25-60 to EPL225PS12
  - Change a motor from OEM124-GJ600D to G550-S10
  - Addition a pump (VP01-1); VP01-1 is different only a header, compared to changed pump (VP01)

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. The 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.

The VIVA combo RF system consists of S_VCS_F, MRFALogger and VIVALogger software.
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 the RF output parameter (power, impedance, current, temperature and energy).
VIVALogger software can be stored and monitored on a tablet PC the RF output parameter (power, impedance, current, temperature and energy).

6. Intended Use [21 CFR 807.92(a)(5)]

The intended use has not changed as a result of the modification and is as follows:

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

7. Technological Characteristics [21 CFR 807.92(a)(6)]

The VIVA combo RF System is substantially equivalent to legally marketed predicate device with respect to indications for use and technology characteristics. The table below presents side by side comparisons for each major component of each device:

Parameter		Subject Device	Predicate Device	Remark
510(K) Number		Not Known	K163450	-
Manufacturer		STARmed Co., Ltd.	STARmed Co., Ltd.	-
Model Name		VIVA combo RF System	VIVA combo RF System	-
Classification Name		Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	same
Classification Panel		General and Plastic Surgery	General and Plastic Surgery	same
Classification Regulation		21 CFR 878.4400	21 CFR 878.4400	same
Product Code		GEI	GEI	same
Device Class		Class II	Class II	same
Intended Use		The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	same
Prescription or OTC		Prescription	Prescription	same
Energy Used		Radiofrequency	Radiofrequency	same
Electrosurgical Unit				
Output Frequency		480 kHz ± 10 %	480 kHz ± 10 %	same
Drive on Time		Up to 30 minutes	Up to 30 minutes	same
Maximum Power Output		Up to 200 watts @ 50 ohms	Up to 200 watts @ 50 ohms	same
Impedance Monitoring		Available	Available	same
Temperature Monitoring		Available	Available	same
Dimension (W x L x H)		260 x 348 x 115 mm	260 x 348 x 115 mm	same
Isolation of USB/Foot Switch PCB		Apply	Not apply	different
Fuse		F 5AH 250 V	T 5AL 250 V	different
Miscellaneous accessories				
Peristaltic Pump	Model	VP01 and VP01-1	VP01	different
	SMPS	EPL225PS12	ECS25-60	different
	Motor	G550-S10	OEM124-GJ600D	different
Hospital-grade power cable		Included	Not included	different
Foot Switch Connect Type		Female	Male	different
Software				
S_VCS_B	Version	1.11F	1.10	different
	Cut-Off in temperature mode	at 15 ohms	at 25 ohms	different
MRFALogger	Version	1.41	1.10	different
VIVALogger	Version	3.30	2.20	different
Active Accessory				
Monopolar/Bipolar		Monopolar	Monopolar	Same
Diameter		17 Gauge	17 Gauge	Same
Sterilization		Ethylene Oxide	Ethylene Oxide	Same
Shelf Life		3 years	3 years	Same
Biocompatibility		ISO 10993-1	ISO 10993-1	Same

	- Cytotoxicity - Intracutaneous Irritation - Sensitization - Systemic Toxicity - Pyrogen test	- Cytotoxicity - Intracutaneous Irritation - Sensitization - Systemic Toxicity - Pyrogen test	

8. Substantial Equivalence [21 CFR 807.92(b)]

When compared to the predicate device (K163450), the VIVA combo RF System presented in this submission has the same:

- Intended Use
- Technological characteristics
- Operating principle
- Energy Used
- Design features
- Physical specifications
- Sterilization
- Shelf Life
- Biocompatibility

A few differences are as follows

- Isolation of USB/Foot Switch PCB
- Fuse
- Peristaltic Pump
- Foot switch Connect Type
- Software

There are no significant differences between the VIVA combo RF System and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

Difference in the isolation of USB PCB and Foot Switch PCB

The changed subject device is applied an isolation of USB PCB and Foot Switch PCB using DC-DC Converter and Digital Isolators. The change in the isolation affects the electrical safety and electromagnetic compatibility. Therefore, the electrical safety and electromagnetic compatibility testing were conducted, the changed subject device was qualified with electrical safety according to IEC 60601-1, IEC 60601-2-2 and electromagnetic compatibility according to the IEC 60601-1-2.

Difference in the Fuse

The main fuse has been changed. The change in the fuse affects the electrical safety and electromagnetic compatibility. Therefore, the electrical safety testing was conducted, the changed subject device was qualified with electrical safety according to IEC 60601-1 and IEC 60601-2-2.

Difference in the peristaltic pump
The SMPS board and motor of the pump have been changed, and another pump (VP01-1) which is different only a pump header has been added. The change in the peristaltic pump affects the electrical safety and electromagnetic compatibility. Therefore, the electrical safety and electromagnetic compatibility testing were conducted, the changed subject device was qualified with electrical safety according to IEC 60601-1, IEC 60601-2-2 and electromagnetic compatibility according to the IEC 60601-1-2

Difference in the foot switch connect type
The connect type of foot switch has been changed from male to female type. The change in the connect type does not affect the electrical safety and efficacy because the female connect type cannot be contacted with an operator; the female connect is not accessible part.

Difference in the software
S_VCS_F software has been changed that RF current is cut-off at 15 ohms in the temperature mode (previous version: cut off at 25 ohms). The change in the software affects the function of subject device. Therefore, the software verification and validation were conducted and performance test which verify the automatically cut-off at 15 ohms. The result of test provide that the change does not raise new safety or effective issues.
Also, the interface of MRFALogger software has been changed and VIVALogger software has been changed to support different screen size for tablet PC. The change in the software does not affect the function of subject device.

Due to these identical clauses and high similarities, the VIVA combo RF System is at least as safe as and as effective as the predicate device. The differences between the subject device and the predicate device do not raise new safety or effectiveness issues as explained above. Based on the electromagnetic compatibility and electrical safety testing, performance testing, and the comparison to predicate devices, the VIVA combo RF System is substantially equivalent to the previously cleared predicate devices.

9. Summary of Non-Clinical Data [21 CFR 807.92(b)(1)]

- Electrical Safety, Electromagnetic Compatibility and Performance:
  Bench tests were conducted to verify that the proposed device met all design specifications.
  The test results demonstrated that the proposed device complies with the following standards:

  - Testing to confirm compliance with the safety requirements of standard AAMI ANSI ES60601-1
  - Testing to confirm compliance with particular requirements of standard IEC 60601-2-2
  - Testing to confirm compliance with EMC requirements of standard IEC 60601-1-2

- Software Validation
  The VIVA combo RF System contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

The VIVA combo RF System complies with the following international and FDA-recognized consensus standards:

AAMI ANSI 60601-1:	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD, Edition 3.1)
IEC 60601-2-2:	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (Edition 6)

IEC 60601-1-2:	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 4)

10. Summary of Clinical Data [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

11. Conclusion [21 CFR 807.92(b)(3)]

The subject device is substantially equivalent to the currently marketed and predicate device in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, substantial equivalence was demonstrated through the non-clinical performance, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 60601-1, IEC 60601-2-2, IEC 60601-1-2 and bench testing, which complied with the requirements specified in the CDRH's Guidance for Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery.

The results of these tests demonstrate that VIVA combo RF System meets the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, electrical safety and electromagnetic compatibility testing demonstrates that the device is substantially equivalent to the previously cleared predicate devices.