March 14, 2018

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

Re: K172012
Trade/Device Name: Star RF Electrode, VIVA RF Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 9, 2018
Received: February 12, 2018

Dear Jun-Young 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

David Krause -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172012

Device Name
star RF Electrode, VIVA RF Electrode

Indications for Use *(Describe)*
star/VIVA RF Electrode 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)]

06/30/2017

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

Name of Sponsor:	STARmed Co.,Ltd.
Address:	B-dong, 4F, 158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si, Gyeonggi-do, Republic of Korea
Contact Name:	Jun-Young Jung
	Telephone #: +82-70-4673-8657
	Fax #: +82-31-816-4546
	Email: jjy3412@starmed4u.com
Registration Number:	3013557681
Name of Manufacturer:	Same as Sponsor

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

Model Name:	star RF Electrode, VIVA RF Electrode
Common Name:	Electrosurgical Cutting and Coagulation Accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Device Class:	2
Review Panel:	General and Plastic Surgery

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:	2

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

The star/VIVA RF Electrodes are a sterile, single-use electrosurgical accessory intended to be used in conjunction with VIVA combo RF generator (K163450). They are not intended to function with other RF generators. The star/VIVA RF Electrodes consists of the tubing set, PC pipe, PC plug and grounding pad. The grounding pad is FDA cleared (K163450).

The star/VIVA RF Electrodes consist of an electrode tip, insulation part, handle and tubing. Patient contacting materials of star RF Electrode are stainless steel 304 and polyester, and patient contacting materials of VIVA RF Electrode are stainless steel 304 and polyimide. 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 star/VIVA RF Electrodes are available in different lengths, different tip exposures and different thicknesses. The lengths that are available for the star RF Electrode range from 7 cm to 20 cm and VIVA RF Electrode range from 15 cm to 20 cm. The tip exposures available for the star RF Electrode range from 5 mm to 20 mm and VIVA RF Electrode range from 5 mm to 30 mm. The exposed length of the VIVA RF Electrode can be adjusted by the control button on the handle. The diameters available for the star RF Electrode diameters are 17 Gauge and 18 Gauge. The diameters available for the VIVA RF Electrode diameters are 15 Gauge and 17 Gauge.

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

star/VIVA RF Electrode is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.

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

The star/VIVA RF Electrodes consist of an electrode tip, insulation part, handle and tubing. The electrode tip of star RF Electrode is composed of stainless steel 304 and polyester, and the electrode tip of VIVA RF Electrode is composed of stainless steel 304 and polymide. 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 conductive electrode tip delivers high frequency current onto a target tissue for coagulation and/or ablation during a surgical operation.

The subject device is substantially equivalent to the predicate device in intended use and technological characteristics. There is no significant difference between the star/VIVA RF Electrodes and the predicate device that would adversely affect the use of the product.

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

Parameter		Subject Device		Predicate Device
510(k) Number		Unknown		K163450
Model Name		star/VIVA RF Electrodes		star RF Electrodes (17-15s30F, 17-20s30F)
Manufacturer		STARmed Co., Ltd.		
Common Name		Electrosurgical Cutting and Coagulation Accessories		
Classification Name		Electrosurgical, Cutting & Coagulation & Accessories		
Classification Panel		General and Plastic Surgery		
Classification Regulation		21 CFR 878.4400		
Product Code		GEI		
Device Class		Class II		
Intended Use		star/VIVA RF Electrode is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.		star RF Electrode is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.
Energy Used		Radiofrequency		Radiofrequency
Operation Principle		Monopolar		Monopolar
Physical Specifications	Electrode Length (mm)	star RF	70, 150, 200	150, 200
		VIVA RF	150, 200	
	Exposure Length (mm)	star RF	5, 7, 10, 20	30
		VIVA RF	5, 10, 15, 20, 25, 30	
	Diameters (Gauge)	star RF	17, 18	17
		VIVA RF	15, 17	
Patient Contacting Materials	Electrode Tip Materials	Stainless **S**teel 304		Stainless **S**teel 304
	Insulation Part Materials	star RF	Polyester	Polyester
		VIVA RF	Polyimide	
Neutral Electrodes	Conductive or Capacitive	Conductive		Conductive
	Physical specifications	187 x 145 (mm)		187 x 145 (mm)
	Materials (Conductive area)	Hydrogel		Hydrogel
Sterile		EO Sterilization		EO Sterilization
Single Use		Single Use		Single Use

Parameter	Subject Device	Predicate Device
Connector Type	4 Pin	4 Pin

When compared to the predicate devices (K163450), the star/VIVA RF Electrodes presented in this submission has the same of the followings:

- Intended Use
- Technological Characteristics
- Energy Used
- Operation Principle
- Sterile
- Single Use
- Connector Type

A few differences are as follows

- Physical Specifications
- Patient Contacting Materials (VIVA RF Electrode)

There is no significant difference between the star/VIVA RF Electrodes and the predicate device that would adversely affect the use of the product. The subject device is substantially equivalent to the predicate device in intended use, technological characteristics, used energy, operation principle, sterile and single use.

Even though the physical specifications and patient contacting materials of the predicate device and the subject device are different, the results of the safety testing for active electrode (IEC 60601-2-2 and AAMI HF 18), bench testing, ex vivo testing (thermal effects on tissue) and biocompatibility testing proved that the subject devices are substantially equivalent to the predicate device.

9. Summary of Non-Clinical Data

The non-clinical performance tests were conducted to evaluate the effectiveness and safety of the star/VIVA RF Electrodes and its equivalence to the predicate device. A drop test, bending force test, electric conduction and flow rate test were performed to minimize the risks associated with mechanical failure and short circuiting. The temperature monitoring test was performed to demonstrate that the temperature sensing.

The test on thermal effects was performed to evaluate the width and depth of thermally damaged zone in relation to the tip length, gauge, power setting, and duration of activation for different tissue types. The test was performed on liver, kidney, and muscle tissue according to the FDA Guidance 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery'.

star/VIVA RF Electrodes comply with the following international and FDA-recognized consensus standards:

IEC 60601-2-2:	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
AAMI HF 18:	Electrosurgical Devices
ISO 10993-1:	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11:	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

The IEC 60601-2-2 standard only applies to the sections (101.3) and the AAMI HF 18 standard only applies to the sections (5.2 and 5.5) since the subject device only consists of active electrodes.

The non-clinical tests all met the acceptance criteria specified in the standards.

10. Summary of Clinical Data

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 devices 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, IEC60601-2-2, AAMI HF 18, ISO 10993-5, ISO 10993-10, ISO 10993-11, bench testing and ex vivo testing (thermal effects on tissue), 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 star/VIVA RF Electrodes meet the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing demonstrates that the device is as safe and effective as the predicate device and performs as well as the predicate device.