DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 8, 2017

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

Re: K163450
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: March 3, 2017
Received: March 7, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -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)*

K163450

Device Name

VIVA combo RF System

Indications for Use *(Describe)*

The VIVA combo RF Ablation 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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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Gyeonggi-do, Republic of Korea

510(k) Summary

[As required by 21 CFR 807.92]

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

December 6, 2016

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 No.: +82 70-4673-8628
  - Fax No.: +82 31-816-4546
  - Email Address: jjy3412@starmed4u.com

- Registration Number: In process

- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

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

- Trade Name: VIVA combo RF System
- Common Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Classification:

Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Classification Regulation	21 CFR 878.4400
Product Code	GEI
Device Class	II

B-dong, 4F, 158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si,
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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate Device

- 510(k) Number: K042216
- Applicant: Valleylab
- Regulation Name: Electrosurgical cutting and coagulation device and accessories
- Trade Name: Cool-tip™ RF Ablation System

There are no significant differences between 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 indications for use and technology characteristics.

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

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 generator 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.

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

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

B-dong, 4F, 158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si,
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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:

Item	Proposed Device	Primary Predicate
K Number	Not known	K042216
Model	VIVA combo RF System	Cool-tip™ RF Ablation System
Manufacture	STARmed Co., Ltd.	Valleylab
Intended Use	The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	The Cool-tip™ RF Ablation System (Generator and Accessories) is intended for use in percutaneous, laparoscopic and intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions.
Type of Use	Prescription Use	Prescription Use
Component	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal
Electrosurgical Unit		
Output Frequency	480 kHz ± 10 %	480 kHz ± 10%
Drive on Time	Up to 30 minutes	Up to 30 minutes
Maximum Power Output	Up to 200 watts @ 50 ohm	Up to 200 watts @ 50 ohm
Active Accessory		
Monopolar / Bipolar	Monopolar	Monopolar

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Non-clinical Test Summary

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

- 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.

- Biocompatibility

  The following biocompatibility tests were performed:

  - Cytotoxicity
  - Irritation/intracutaneous reactivity
  - Sensitization
  - Acute Systemic Toxicity

- Sterilization and Shelf Life

  The active electrode of VIVA combo RF System is delivered in a sterile state and is intended for single use only. The sterilization method used is ethylene oxide and this device has a shelf life of 3 years.

Clinical Test Summary

No clinical studies were considered necessary and performed.

B-dong, 4F, 158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si,
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8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate devices, the VIVA combo RF System in this submission presented the same in terms of indications for use, components and technology characteristics.

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

In according to with the Federal food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification STARmed Co., Ltd. concludes that VIVA combo RF System is substantially equivalent in safety and effectiveness to predicate device as described herein.