September 4, 2018

STARmed Co., Ltd.
Mr. Jun-Young Jung
B-dong, 4F, 158, Haneulmaeul-ro, IlsanDong-gu
Goyang-si, 10355 Kr

Re: K181249
Trade/Device Name: EUSRA RF Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, JOS
Dated: June 21, 2018
Received: June 27, 2018

Dear Mr. 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. 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,

Jennifer R. Stevenson -S3

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)*
K181249

Device Name
EUSRA RF Electrode

Indications for Use *(Describe)*
The EUSRA RF Electrode is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

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)]

06/21/2018

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:	EUSRA RF Electrode
Common Name:	Electrosurgical Cutting and Coagulation Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, JOS
Device Class:	2

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

510(k) Number:	K150029
Applicant:	EMcision LTD.
Model Name:	Habib EUS RFA 6700
Common Name:	Monopolar electrosurgical device
Classification Name:	Electrosurgical Cutting and Coagulation device
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, JOS
Device Class:	2

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

The EUSRA RF Electrode is a monopolar electrode. The EUSRA RF Electrode is 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 EUSRA RF Electrode consists of the tubing set and grounding pad. The grounding pad is FDA cleared (K163450).

The EUSRA RF Electrode consists of an electrode tip, insulation part, handle. Patient contacting materials of EUSRA RF Electrode are stainless steel 304, polyimide, polyether block polyamide copolymer and PTFE. Cooling of the EUSRA RF 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 length of the flexible tube, tip exposures length and diameter of EUSRA RF Electrode are available as in the following table:

Model Name	Flexible Length (mm)	Tip Exposure Length (mm)	Gauge
19-05E	1393 ± 20	05	19
19-07E	1393 ± 20	07	19
19-10E	1393 ± 20	10	19
19-15E	1393 ± 20	15	19
19-20E	1393 ± 20	20	19

The exposed length of the EUSRA RF Electrode can be adjusted by the exposure length controller on the handle.

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

The EUSRA RF Electrode is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

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

The EUSRA RF Electrode consists of an electrode tip, insulation part, handle and tubing. Patient contacting materials of EUSRA RF Electrode are stainless steel 304, polyimide, polyether block polyamide copolymer and PTFE. Cooling of the EUSRA RF 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.

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

Parameter		Subject Device	Predicate Device
510(k) Number		Unknown	K150029
Model Name		EUSRA RF Electrode	Habib EUS RFA 6700
Manufacturer		STARmed Co., Ltd.	EMcision Ltd.
Common Name		Electrosurgical Cutting and Coagulation Accessories	Monopolar electrosurgical device
Classification Name		Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Panel		General and Plastic Surgery	General and Plastic Surgery
Classification Regulation		21 CFR 878.4400	21 CFR 878.4400
Product Code		GEI, JOS	GEI, JOS
Device Class		Class II	
Intended Use		The EUSRA RF Electrode is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.	The habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjuntion with compatible radio frequecny generator.
Energy Used		Radiofrequency	Radiofrequency
Operation Principle		Monopolar	Monopolar
Physical Specifications	Tip Length	5, 7, 10, 15, 20 mm	20mm
	Tip Diameters	19 Gauge	19 Gauge, 22 Gauge
	Flexible Shaft Length	1393 mm	2200 mm
Patient Contacting Materials		Stainless Steel 304, Polyimide, Polyether Block Polyamide Copolymer, Stainless Steel 304 and PTFE	Stainless Steel, PTFE
Neutral Electrodes for EUSRA RF Electrode	Conductive or Capacitive	Conductive	Not Known
	Physical specifications	187 x 145 (mm)	
	Materials (Conductive area)	Hydrogel	
Sterile		EO Sterilization	Gamma Irradiation
Single Use		Single Use	Single Use
Extensible Tip Length		Extensible Tip Length	Not Extensible Tip Length

When compared to the predicate device (K150029), the EUSRA RF Electrode presented in this submission has the same of the followings:

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

A few differences are as follows

- Physical Specifications
- Patient Contacting Materials
- Neutral Electrodes
- Extensible Tip Length

There is no significant difference between the EUSRA RF Electrode 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.

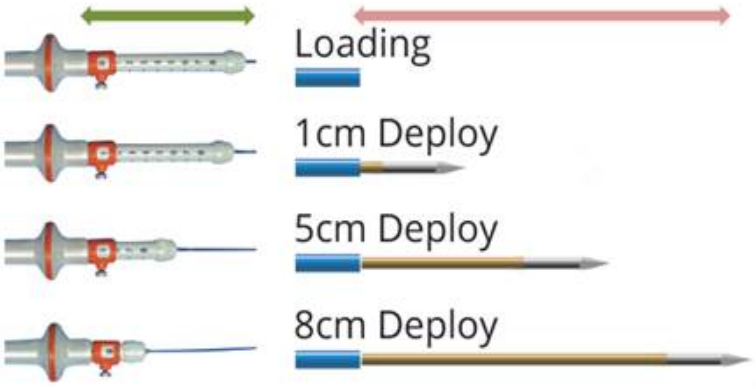
Difference in the electrode length and the flexible shaft length
The difference in the electrode length for the subject device does not affect the efficacy because the subject device utilized the same technology of Monopolar RF with the same purpose. Generally, the efficacy of the device for the intended use is affected by the method of RF delivery, output power and the area of the tip; the difference in the electrode length does not affect these factors. Therefore, the difference in the electrode length does not affect the efficacy of the subject device. Furthermore, the subject device is qualified with electrical safety according to IEC 60601-1, IEC 60601-2-2 and IEC 60601-2-18 and electromagnetic compatibility according to the IEC 60601-1-2.

Difference in the tip diameters
The difference in the tip diameters for the subject device affects the area of the ablation, but does not affect the method of RF delivery and output power, which is affected by the efficacy. These factors were taken into account when designing the ex vivo testing (thermal effects on tissue), the results of the test provide that the efficacy of the subject device was not affected. Furthermore, the subject device is qualified with electrical safety according to IEC 60601-1, IEC 60601-2-2 and IEC 60601-2-18 and electromagnetic compatibility according to the IEC 60601-1-2.

Difference in the neutral electrode
The subject device is used with a different neutral electrode than the predicate device. However, The neutral electrode is FDA cleared (K163450). Therefore, the difference between the subject device and the predicate device do not raise new safety or effectiveness issues.

Difference in the extensible tip length

The ESURA RF Electrode has extendable function that enables the exposure length of to be changed. The exposure length can be adjusted manually by the length controller as the picture below. The performance testing for extensible tip and insulation part was conducted in order to verify the adjustable length for each stage.



In addition, the extensible length of the subject device does not affect the method of RF delivery and output power, which is affected by efficacy. These factors were taken into account when designing the ex vivo testing (thermal effects on tissue), the results of the test provide that the efficacy of the subject device was not affected. Furthermore, the subject device is qualified with electrical safety according to IEC 60601-1 and IEC 60601-2-2 and electromagnetic compatibility according to the IEC 60601-1-2.

Due to these identical clauses and high similarities, the ESURA RF Electrode 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 device, the ESURA RF Electrode is substantially equivalent to the previously cleared predicate device.

9. Summary of Non-Clinical Data

The non-clinical performance tests were conducted to evaluate the effectiveness and safety of the EUSRA RF Electrode and its equivalence to the predicate device. A drop test, bending force test and length control test were performed to minimize the risks associated with mechanical failure.

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’.

EUSRA RF Electrode complies with the following international and FDA-recognized consensus standards:

IEC 60601-1:	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-2-2:	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
IEC 60601-2-18:	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
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 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 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 and IEC 60601-2-18, ISO 10993-5, ISO 10993-10, ISO 10993-11, bench testing, drop 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.