April 11, 2019

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

Re: K181758
Trade/Device Name: ELRA Electrode
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: March 11, 2019
Received: March 13, 2019

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. 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,

Shanil P. Haugen -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K181758

Device Name
ELRA Electrode

Indications for Use *(Describe)*
The ELRA Electrode is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts.

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)]

03/11/2019

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:	STARmed Co.,Ltd.

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

Trade Name:	ELRA Electrode
Common Name:	Endoscopic Electosurgical Unit
Classification Name:	Endoscopic Electrosurgical Unit and Accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KNS
Device Class:	Ⅱ

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

510(k) Number:	K180165
Applicant:	EMcision LTD.
Trade Name:	Habib EndoHPB
Common Name:	Endoscopic Electosurgical Unit
Classification Name:	Endoscopic Electrosurgical Unit and Accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KNS
Device Class:	Ⅱ

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

The ELRA Electrode is a bipolar electrode. ELRA 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 ELRA Electrode consists of an electrode tip, insulation part, handle. Patient contacting materials of ELRA Electrode are stainless steel 304, Teflon-ETFE, UV adhesive, Nylon, PEEK and polyether block amides.

The lengths of the flexible tube available for the ELRA Electrode length are 400 mm and 1,750 mm. The tip exposures available for the ELRA Electrode length are 11 mm, 18 mm, 22mm and 33 mm. The diameter available for the ELRA Electrode diameters is 7 French.

The model with longer length(1,750 mm) are used with endoscopes. This electrode is inserted into the body through the oral rout, and are used at the application site. The shorter length(400 mm) models are performed by percutaneous resection directly at the site of application.
Both methods have to be used with fluoroscopy during the procedure.

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

The ELRA Electrode is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts.

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

The ELRA Electrode consists of an electrode tip, insulation part, handle. Patient contacting materials of ELRA Electrode are stainless steel 304, Teflon-ETFE, UV adhesive, Nylon, PEEK and polyether block amides.

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 ELRA Electrode 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	K181758	K180165
Trade Name	ELRA Electrode	Habib EndoHPB
Manufacturer	STARmed Co., Ltd.	EMcision LTD.
Common Name	Endoscopic Electrosurgical Unit	Endoscopic Electrosurgical Unit
Classification Name	Endoscopic Electrosurgical Unit and Accessories	Endoscopic Electrosurgical Unit and Accessories

Parameter		Subject Device	Predicate Device
Classification Panel		Gastroenterology and Urology	Gastroenterology and Urology
Classification Regulation		21 CFR 876.4300	21 CFR 876.4300
Product Code		KNS	KNS
Device Class		Class II	
Intended Use		The ELRA Electrode is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts.	The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts. The Habib EndoHPB is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear occluded stent.
Energy Used		Radiofrequency	Radiofrequency
Operation Principle		Bipolar	Bipolar
Physical Specifications	Tip Length	11, 18, 22, 33 mm	Two 8 mm electrodes
	Tip Diameters	7 French	2.7 mm (8 French)
	Flexible Shaft Length	400, 1750 mm	1800 mm
	Electrode exposed sites	2 part (active electrode: 1/ return electrode: 1) 4 part (active electrode: 2/ return electrode: 2)	2 part (active electrode: 1/ return electrode: 1)
Patient Contacting Materials		Stainless Steel 304, Teflon-ETFE, UV adhesive, Nylon, PEEK, and Polyether Block Amides	Stainless Steel, Pebax & Stainless Steel
Sterile		EO Sterilization	EO Sterilization
Single Use		Single Use	Single Use
Temperature Sensor		Available	Not Known

Parameter		Subject Device	Predicate Device
Electrical Safety		IEC 60601-1 IEC 60601-2-2	IEC 60601-1 IEC 60601-2-2
Performance	Conduction	Conduct electricity between circuits	Conduct electricity between circuits
	Impedance	within 5Ω	within 5Ω
	Short-circuit	Active Tip and Receive Tip are short-circuited	Active Tip and Receive Tip are short-circuited
	Opening condition of the wire guide wire passage.	No distortion and blockage	No distortion and blockage

When compared to the predicate devices (K180165), the ELRA Electrode presented in this submission have the same of the followings:

- Intended Use
- Technological Characteristics
- Energy Used
- Operation Principle
- Sterile
- Single Use
- Electrical Safety
- Performance (conduction, impedance, short-circuit and opening conduction)

A few differences are as follows

- Physical Specifications
- Patient Contacting Materials
- Temperature Sensor
- Electrode exposed sites

There is no significant difference between the ELRA 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 devices does not affect the efficacy because the subject devices utilized the same technology of Bipolar 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 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 thermal effects testing was completed to demonstrate the substantially equivalent ablation performance of the subject device and predicate device. The results demonstrated that the subject device is substantially equivalent to those obtained with the predicate device. Furthermore, the subject device is 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 temperature sensor

The temperature sensor measures a temperature of a tissue in the near the sensor, and to be used automatically cut off the current in instances of excessive heat. The performance testing was conducted in order to demonstrate a function of temperature sensor in the subject device.
In addition, the temperature sensor 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 provided that the efficacy of the subject device was not affected.

Difference in the electrode exposed sites

The subject device has 2 or 4 exposed electrodes. A bipolar electrosurgical system basically requires two electrodes (active and return). The reason for adding four electrodes is to assist ablation by more uniform energy by reducing the distance between the active electrode and the return electrode when ablation of the long electrode is performed. Basically there is no difference in using active and return.

Due to these identical clauses and high similarities, the ELRA 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 including predicate comparative testing, and the comparison to predicate devices, the ELRA Electrode is substantially equivalent to the previously cleared predicate devices.

9. Summary of Non-Clinical Data

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

ELRA 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
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

A clinical trial of stent insertion using a subject device was conducted in 30 patients. Clinical trials were conducted for 120 seconds at a power of 7 w or 12 w to deliver 80 degrees of heat to the lesion tissue. The stenting procedure was successful and had three minor inflammatory reactions, but no direct side effects associated with the device. Clinical trials have concluded that this product is safe and effective.

In a retrospective study of 10 patients with malignant biliary hilar duct obstruction who underwent percutaneous intraductal RFA using 400mm electrode followed by dual stent placement, percutaneous intraductal RFA followed by dual stent placement was successful in all patients. There is no major complications were identified.

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, IEC 60601-1, IEC 60601-2-2 and ISO 10993-5, ISO 10993-10, ISO 10993-

11, bench testing, drop testing, temperature monitoring 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 ELRA Electrode meets 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.