October 25, 2023

STARmed Co., Ltd.
% Bobae Jung
General Manager
JNM Korea
#207, #206 Building, Gunpo IT Valley
17, Gosan-ro 148beon-gil
Gunpo-si, 15850
South Korea

Re: K233113
Trade/Device Name: ELRA Electrode (7-2B11S, 7-2B11L, 7-2B22S, 7-2B22L, 7-4B18S, 7-4B18L, 7-4B33S, 7-4B33L)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: September 26, 2023
Received: September 27, 2023

Dear Bobae 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233113

Device Name

ELRA Electrode (7-2B11S, 7-2B11L, 7-2B22S, 7-2B22L, 7-4B18S, 7-4B18L, 7-4B33S, 7-4B33L)

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Special 510(k) Summary

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

1. Date Prepared

26/09/2023

2. Submitter's Information

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:	Honggen Lee Telephone #: +82-10-2363-4998 Fax #: +82-31-816-4546 Email: lhg1186@starmed4u.com
Registration Number:	3013557681
Name of Manufacturer:	STARmed Co.,Ltd.

3. Device information

Trade Name:	ELRA Electrode
Model Name:	7-2B11S, 7-2B11L, 7-2B22S, 7-2B22L, 7-4B18S, 7-4B18L, 7-4B33S, 7-4B33L
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. Primary predicate Device

Endoscopic Electro surgical Unit, Endoscopic Electrosurgical Unit and Accessories, K181758

5. Purpose to submission

This special 510(k) premarket notification is submitted to expand shelf-life of ELRA electrode from 1 year to 3 years.

6. Description of the Device

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.

7. Indications for 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.

8. Technological Characteristics

No changes have been made to the technological characteristics of the device.

9. Comparison to the Predicate Device

The modified device has long-term shelf-life comparing with previous one.
There are no other design changes with this 510(k).

Subjective device and predicate device have incorporate substantially equivalent design, materials, technology, manufacturing process, sterilization process and intended use as those featured in the predicate.
The one thing different from predicate is shelf-life.

- Shelf life

There is no significant difference between the ELRA Electrode and the predicate device(K181758) have the same technological characteristics (device design, sterilization and biocompatibility). The subject device modification consists of shelf life from 1 year to 3 years.
The subject device is substantially equivalent to the predicate device in intended use, technological characteristics, used energy, operation principle, sterile under same manufacturing process condition as well.
Any difference between the subject device and the predicate device are considered shelf life which can be proved by performance of real-time aging. Changing shelf-life does not raise concerning safety or effectiveness questions.

10. Performance test

Performance testing has been completed to demonstrate that updated shelf-life of subject device meets the safety and performance requirements established in the design specifications.

<Sterile packaging integrity testing>
ISO11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

ASTM F1140/F1140M-13(2020)e1 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1608-21 Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
ISO 11135:2014/Amd1:2018 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
ISO 10993-7:2008/Amd1: 2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]

<Performance testing>
IEC60601-2-2:2017 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
- HF leakage.
- HF dielectric strength.
- mains frequency dielectric strength.

ASTM D882-18 Standard Test Methods for Tensile Properties of Thin Plastic Sheeting
ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials

11. Summary of Non-Clinical Test

Determination of substantial equivalence is based on an assessment of non-clinical performance bench testing data.

12. Summary of Clinical test

The clinical testing was not performed as performance studies were sufficient to support substantial equivalence.

13. Conclusion

Based on above, the subject device is substantially equivalent to the currently marketed and predicate devices(K181758) in respect of safety and effectiveness.