March 15, 2021

Micro-Tech (Nanjing) Co., Ltd.
Cecilia Sun
RA Engineer
No. 10 Gaoke Third Road
Nanjing, Jiangsu Province 210032
CHINA

Re: K202438
Trade/Device Name: Ensure Single-Use Coagulation Forceps
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KGE
Dated: February 9, 2021
Received: February 12, 2021

Dear Cecilia Sun:

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/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 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 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,

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.

510(k) Number *(if known)*
K202438

Device Name
Ensure(TM) Single-Use Coagulation Forceps

Indications for Use *(Describe)*
These instruments have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510K Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. **Date of Preparation: 2020-05-27**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

Establishment Registration Number: 3004837686

Contact Person: Cecilia Sun

Position: RA Engineer

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Email: RA.Micro-Tech@outlook.com

3. **Identification of Proposed Device**

Trade Name: Ensure™ Single-Use Coagulation Forceps

Common Name: Electrosurgical Hemostatic Forceps

Regulatory Information

Classification Name: Endoscopic electrosurgical unit and accessories

Classification: 2

Product Code: KGE

Regulation Number: 876.4300

Review Panel: Gastroenterology and urology

4. Identification of Predicate Device

510(k) Number: K062517

Product Name: Single-Use Electrosurgical Hemostatic Forceps

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORPORATION

5. Indications for Use

These instruments have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

6. Device Description

The proposed Ensure™ Single-Use Coagulation Forceps is a sterile, single-use endoscopic device, intended to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract. The proposed device is only for adult patients.

The Coagulation Forceps is a hemostasis device which combines both mechanical property and energy. It consists of a jaw, coated spring sheath, high frequency electrical interface and handle. The Coagulation Forceps can be advanced through an appropriate endoscope channel to reach targets and by pushing and pulling its Finger Ring of the handle, the forceps opens and closes. The bleeding point will be clamped with the Coagulation Forceps. At that point, high-frequency and high-voltage power will be delivered at the precise site of bleeding using an electrosurgical current generator so as to achieve hemostasis. The proposed devices are EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf life of 2 years.

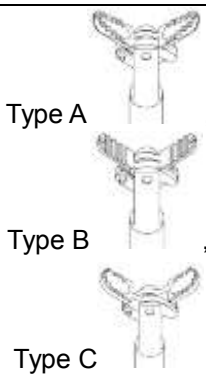
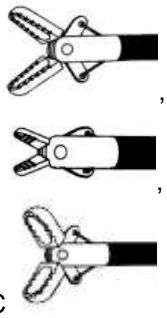
7. Comparison of Technological Characteristics

The **Ensure™ Single-Use Coagulation Forceps** incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology,

sterilization process and intended use as those featured in the predicate device -

Single-Use Electrosurgical Hemostatic Forceps.

Comparison to predicate Devices:

Item	Proposed Device **Ensure™ Single-Use Coagulation Forceps**	Predicate Device **Single-Use Electrosurgical Hemostatic Forceps (K062517)**	Remark
Product Code	KGE	KGE	Same
Regulation No.	876.4300	876.4300	Same
Class	2	2	Same
Supplied in Sterile	Yes	Yes	Same
Main Material	17-4ph, SUS303F, SUS304, HDPE, FEP	Stainless steel, Polyethylene	Similar
Configuration	Jaws, Tube, Plug, Slider	Forceps, Tube, Plug, Slider	Same
Working length	1650mm and 2300mm.	1650mm, 1950mm and 2300mm	Similar
Jaws Type	 Type A , Type B , Type C	 Type A , Type B , Type C	Same
Maximum Diameter	≤2.7 mm	⩽2.75 mm / ⩽3.1 mm	Similar
Energy Used/Delivered	Monopolar Radio Frequency Current.	Monopolar Radio Frequency Current.	Same
Rated High-Frequency Voltage	COAG: 2300 Vp (4600 Vp-p)	COAG: 2900 Vp (5800 Vp-p)	Different
Biological Performance	Conform to ISO 10993-1	Conform to ISO 10993-1	Same
Electrical Safety and Electromagnetic Compatibility	Conform to: IEC60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-2-18	Conform to: IEC60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-2-18	Same
Indications for	These instruments have been designed	These instruments have been	Same

Section 5 510k summary

Item	Proposed Device **Ensure™ Single-Use Coagulation Forceps**	Predicate Device **Single-Use Electrosurgical Hemostatic Forceps (K062517)**	Remark
Use	to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.	designed to be used with Olympus endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract. Do not use this instrument for any purpose other than its intended use	
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Shelf Life	Two years	Three years	Different
Sterilization	EO Sterilized, SAL:10^{-6}	EO Sterilized, SAL:10^{-6}	Same
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	Same

8. Performance Data

The proposed device the **Ensure™ Single-Use Coagulation Forceps** meets the requirements of ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process”, ISO 11135 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”, and ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”,

The following bench tests were performed on the **Ensure™ Single-Use Coagulation Forceps**

- Dimension Testing
- Rotatable Performance Testing
- Pushability Testing
- Actuation Testing
- The Removal of HF Plug Testing

- Electrode Contact Impedance Testing
- Hemostatic Performance Testing
- Tensile Strength Testing

The tests performed demonstrated that the proposed device and predicate device are substantially equivalent.

Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. Two-year aging test will be performed to demonstrate longer stability and support the results of the accelerated aging test.

Sterilization validation was carried out in accordance with ISO 11135:2014 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”.

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO-10993 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process” issued on June 16,2016.

Electromagnetic compatibility, electric safety, and thermal safety had been confirmed according to the following standards:

IEC60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: Medical electrical equipment – general requirements for the basic safety and essential performance

IEC 60601-2-2:2017 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

IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment

IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic

disturbances - Requirements and tests

9. Animal Study

No animal study is included in this submission.

10. Clinical Study

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Ensure™ Single-Use Coagulation Forceps** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **Single-Use Electrosurgical Hemostatic Forceps (K062517)**.