July 24, 2020

Micro-Tech (Nanjing) Co., Ltd.
Sally He, RA Engineer
No.10 Gaoke Third Road
Nanjing National Hi-Tech, Industrial Development Zone
Nanjing, Jiangsu Province 210032
China

Re: K193601
Trade/Device Name: Single Use Electrosurgical Knife
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: December 19, 2019
Received: December 23, 2019

Dear Sally He:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193601

Device Name

Single Use Electrosurgical Knife

Indications for Use *(Describe)*

These instruments have been designed to be used with endoscopes and electrosurgical for dissection, elevation, irrigation and preparation of tissue layers in combination with monopolar cutting and coagulation 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.

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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: K193601

1. **Date of Preparation: 2020-05-28**

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

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3. **Identification of Proposed Device**

Trade Name: Single Use Electrosurgical Knife

Common Name: Electrosurgical Knife

Regulatory Information

Classification Name: Endoscopic electrosurgical unit and accessories

Classification: 2

Product Code: KNS

Regulation Number: 876.4300

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

Predicate Device

510(k) Number: K171158

Product Name: Single Use Electrosurgical Knife

Manufacturer: Olympus Medical Systems Corporation

Reference device

510(k) Number: K083608

Product Name: ERBE Hybrid Knife™

Manufacturer: ERBE USA, Inc

5. Indications for Use

These instruments have been designed to be used with endoscopes and electrosurgical units for dissection, elevation, irrigation and preparation of tissue layers in combination with monopolar cutting and coagulation within the digestive tract.

6. Device Description

The proposed device Single Use Electrosurgical Knife is a sterile, single-use endoscopic device, intended to be used with endoscopes and electrosurgical units for dissection, elevation, irrigation and preparation of tissue layers in combination with monopolar cutting and coagulation within the digestive tract.

The Single Use Electrosurgical Knife is used with the Electrosurgical Unit (ESU), the ESU supplies high frequency (HF) energy through a retractable electrode of the Single Use Electrosurgical Knife for the cutting and coagulation of tissue. The Single Use Electrosurgical Knife consists of Cutting Knife, outer tube assembly, Middle Tube assembly and handle assembly. Physicians would attach it to the ESU. For endoscopic procedures, the Single Use Electrosurgical Knife is placed down the channel of an endoscope that has a working channel equal to or greater than 2.8mm.

Upon the setup of the ESU, the Single Use Electrosurgical Knife is ready for use. To activate cautery, the Cutting Knife is extended out and the ESU's footswitch is depressed. The subject devices with injection models can supply fluid into the submucosa to supply liquid, use a syringe or pump to connect with luer tap on the hand components.

The Single Use Electrosurgical Knife is divided into I type, T type, O type and IT type according to the shape of the Cutting Knife. The main materials include ABS, Stainless Steel, PTFE, Zirconia, TPU and Gold. The physical and chemical performances of the device are stable. 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 3 years.

The Single Use Electrosurgical Knife has twenty-two (22) specifications; the main differences of these specifications are Cutting Knife Shape, Cutting Knife Length, and Effective Working Length and with injection function or without injection function.

7. Comparison of Technological Characteristics

The **Single Use Electrosurgical Knife** 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 Knife (K171158):**

Item	Proposed Device **Single Use Electrosurgical Knife**	Predicate Device **Single Use Electrosurgical Knife (K171158)**	Remark
Product Code	KNS	KNS	Same
Regulation No.	878.4300	878.4300	Same
Class	2	2	Same
Supplied in Sterile	Yes	Yes	Same
Main Material	PTFE, ABS, SUS304	Polymer materials, Stainless Steel	Similar
Configuration	Cutting Knife, Tube, and	Distal end, Tube, and	Same

Section 5 510k summary-20200528 updated

Item	Proposed Device **Single Use Electrosurgical Knife**	Predicate Device **Single Use Electrosurgical Knife (K171158)**	Remark
	Handle	Handle	
Injection	With/Without Injection	With Injection	Similar
Cutting Knife Shape	I,T,O,IT	T	Similar
Cutting Knife length	1.5mm,2mm,4mm	2mm,1.5mm	Similar
Working Length	1950mm,2350mm	1650mm,1950mm,2300mm	Similar
Compatible endoscopy working channel	≥2.8mm	≥2.8mm	Same
Energy used/ Delivered	Monopolar Radio Frequency Current	Monopolar Radio Frequency Current	Same
Rated High-Frequency Voltage	CUT/COAG:2400Vp-p	CUT: 3200Vp-p COAG: 5800Vp-p	Similar
Indications for Use	These instruments have been designed to be used with endoscopes and electrosurgical for dissection, elevation, irrigation and preparation of tissue layers in combination with monopolar cutting and coagulation within the digestive tract.	These instruments have been designed to be used with Olympus endoscopes, electrolsurgical units to cut tissue and coagulate or to perform hemostasis using high-frequency current and flushing devices for submucosal injection in the digestive tract.	Substantial same
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	Three years	Three years	Same
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Same

Section 5 510k summary-20200528 updated

Item	Proposed Device **Single Use Electrosurgical Knife**	Predicate Device **Single Use Electrosurgical Knife (K171158)**	Remark
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
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

8. Performance Data

Performance testing was conducted to demonstrate the essential performance of the proposed device and confirmed that the proposed device works as intended with the compatible devices. Additionally, the results of the tests below were evaluated as substantially equivalent to the predicate device.

- Dimension
- Actuation Performance
- Compatible Performance
- Sealing Performance
- Flowing Performance
- Mucosa Lift Performance
- Cutting Performance
- Connected Force Performance

The bench testings 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. Three-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 Single Use Electrosurgical Knife 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 Knife (K171158)**.