December 17, 2021

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

Re: K211172
Trade/Device Name: Single Use Electrosurgical Knife with Fluid Pump System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, FQH
Dated: November 3, 2021
Received: November 8, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211172

Device Name
Single Use Electrosurgical Knife with Fluid Pump System

Indications for Use *(Describe)*

Single Use Electrosurgical Knife:
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.

Fluid Pump System:
The Fluid Pump System is a fluid delivery device that can inject fluid with adjustable flow rate and can be used with the Single Use Electrosurgical Knife for elevation of tissue layers by injection into the submucosa.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: **K211172**

1. Date of Preparation: 2021-10-28

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

Contact Person: Sally He

Position: RA Engineer

Tel: +86-25-58646395

Fax: +86-25-58350006

Email: RA.Micro-Tech@outlook.com

3. Identification of Proposed Device

Product Name: Single Use Electrosurgical Knife with Fluid Pump System

Trade Name: Single Use Electrosurgical Knife, **Fluid Pump System**

Common Name: Electrosurgical Knife; Jet

Regulatory Information

Classification Name: Electrosurgical cutting and coagulation device and accessories, Jet lavage.

Classification: 2

Product Code: GEI and FQH

Regulation Number: 878.4400 and 880.5475

Review Panel: General & Plastic Surgery, General Hospital

4. Identification of Predicate Device/Reference Device

Predicate Device

510(k) Number: K193601

Product Name: Single Use Electrosurgical Knife

Manufacturer: Micro-Tech (Nanjing) Co., Ltd

Reference Device

510(k) Number: K143306

Product Name: ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

Manufacturer: ERBE USA, Inc

5. Indications for Use

Single Use Electrosurgical Knife:

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.

Fluid Pump System:

The **Fluid Pump System** is a fluid delivery device that can inject fluid with adjustable flow rate and can be used with the **Single Use Electrosurgical Knife** for elevation of tissue layers by injection into the submucosa.

6. Device Description

The proposed device **Single Use Electrosurgical Knife with Fluid Pump System** includes **Single Use Electrosurgical Knife** and **Fluid Pump System**

The **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 **Fluid Pump System** is a fluid delivery device that can inject fluid with adjustable flow rate and can be used

with the **Single Use Electrosurgical Knife** for elevation of tissue layers by injection into the submucosa. The **Fluid Pump System** is included as an accessory to the **Single Use Electrosurgical Knife**.

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. 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 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.

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 **Fluid Pump System** included in the proposed device is a fluid delivery device that can inject fluid with adjustable flow rate and can be used with the **Single Use Electrosurgical Knife** for elevation of tissue layers by injection into the submucosa.

The **Fluid Pump System** consists of a Foot Pedal, a Fluid Pump Console (with a Power Cord and a Control Button Cord), a Disposable Pump Cartridge, a Disposable Tubing Set, and a Disposable Control Button. The Disposable Pump Cartridge adopts the structure of a reciprocating pump, and the purpose of conveying sterile fluid is achieved through the piston's reciprocating movement. The Disposable Tubing Set is used to connect the Disposable Pump Cartridge's fluid outlet and **Single Use Electrosurgical Knife**'s fluid injection port. The Fluid Pump Console provides a driving force to drive the Disposable Pump Cartridge to achieve reciprocating motion. The user can set the Effect value via the touch button on the touch screen or the physical knob. The Effect setting value range is 10 to 40, where Effect 10 corresponds to the minimum flow rate of 25mL/min, and Effect 40 corresponds to the

maximum flow rate of 100mL/min. When **Fluid Pump System** used with **Single Use Electrosurgical Knife, the recommended Effect is 10-30.** The user can control the fluid delivery through the Foot Pedal or the Disposable Control Button, stepping on the Foot Pedal or pressing the Disposable Control Button to start fluid delivery, releasing the Foot Pedal or the Disposable Control Button, and immediately stop the fluid delivery.

The **Single Use Electrosurgical Knife** 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 one year.

The Disposable Pump Cartridge, Disposable Tubing Set and Disposable Control Button of **Fluid Pump System** 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 one year. The Foot Pedal and Fluid Pump Console of **Fluid Pump System** are non-sterile and reusable, the service life of the Foot Pedal and Fluid Pump Console are 8 years.

7. Comparison of Technological Characteristics

The proposed device **Single Use Electrosurgical Knife with Fluid Pump System** includes **Single Use Electrosurgical Knife** and **Fluid Pump System**. The **Single Use Electrosurgical Knife** is identical to the current Single Use Electrosurgical Knife cleared under K193601. Compared with the predicate device Single Use Electrosurgical Knife cleared under K193601, the only difference of the proposed device is the addition of **Fluid Pump System,** which is included as accessory of **Single Use Electrosurgical Knife.**

For the difference, we cited a reference device ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe (K143306) to compare with the new added accessory **Fluid Pump System.**

Comparison to Reference Devices

Characteristics	**Fluid Pump System**	Reference Device **ERBEJET® 2 System with HybridAPC Probe** (K143306)	**Remark**
Indications for Use	The Fluid Pump System is a fluid delivery device that can inject fluid with adjustable flow rate and can be used with the	The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft	The intended use of the proposed device **Fluid Pump System** is

Characteristics	**Fluid Pump System**	Reference Device **ERBEJET® 2 System with HybridAPC Probe** (K143306)	**Remark**
	Single Use Electrosurgical Knife for elevation of tissue layers by injection into the submucosa.	tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery. The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).	included in the reference device **ERBEJET® 2 System**.
Energy Delivered	Pressurized sterile saline for submucosa lifting	Pressurized sterile saline for cutting, dissecting and submucosa lifting	The energy delivered is included in **ERBEJET® 2 System**.
Power Input	100-240 V	100-240 V	Same
Frequency	50/60 Hz	50/60 Hz	Same
Nozzle Diameter	0.15 mm	0.12 mm	Similar
Flow Rate	25~100 mL/min 25~75 mL/min (Recommend value when used with **Single Use Electrosurgical Knife**)	1~55 mL/min	Similar
Components	Fluid Pump Console Connecting Cables Foot Pedal Disposable Pump Cartridge Disposable Pump Tubing Disposable Control Button	Unit Connecting Cables Foot Switch Pump Cartridge Applicators Suction System	The proposed device doesn't include Applicators and Suction System
Main Material	Metal, Glass Display Screen, Plastics, Wiring, Insulation Plastic, Metal	Metal, Glass Display Screen, Plastics, Wiring, Insulation Plastic, Metal	SE
Mucosal Lift Performance	Deliver flow liquid for mucosal lifting.	Deliver flow liquid for mucosal lifting.	SE
Sealing and	The Product has been found to	The Product has been found to	The proposed

Characteristics	**Fluid Pump System**		Reference Device **ERBEJET® 2 System with HybridAPC Probe** (K143306)		**Remark**
Connection Performance	properly connect and detach from designated equipment/accessory. Once connected, there are no water leaks.		properly connect and detach from designated equipment/accessory. Once connected, there are no water leaks, argon gas leakages, or leakage currents above international standards.		device doesn't include a probe subsystem, without argon gas or currents delivered.
Electrical Performance	Comply with IEC 60601-1:2012; IEC60601-1-2:2014; IEC 60529 (Foot Pedal Only)		Comply with IEC 60601-1:2012; IEC60601-1-2:2014; IEC 60529 (Foot Pedal Only)		SE
Usability	Comply with IEC 60601-1-6:2013; IEC 62366-1:2015;		Comply with IEC 60601-1-6:2013; IEC 62366-1:2015;		SE
Software	Comply with IEC 62304:2015;		Comply with IEC 62304:2015;		SE
Biocompatibility	Comply with ISO 10993-1		Comply with ISO 10993-1		SE
Shelf Life	Fluid Pump Console (with connecting cables), Foot Pedal	Reusable	Unit Connecting cables, Foot Pedal Suction System	Reusable	SE
	Disposable Pump Cartridge, Disposable Pump Tubing, Disposable Control Button	1 Year Comply with ASTM F1980-16	Pump Cartridge, Applicators	3 Years Comply with ASTM F1980-16	
Sterilization	Fluid Pump Console (with connecting cables), Foot Pedal	Non-Sterile	Unit Connecting cables, Foot Pedal Suction System	Non-Sterile	SE
	Disposable Pump Cartridge, Disposable Tubing Set, Disposable Control Button:	EO Sterilization, SAL: 10^{-6}.	Pump Cartridge, Applicators	EO Sterilization, SAL: 10^{-6}.	

Characteristics	**Fluid Pump System**		Reference Device **ERBEJET® 2 System with HybridAPC Probe** (K143306)		**Remark**
Single Use	Fluid Pump Console (with connecting cables), Foot Pedal	Reusable	Unit Connecting cables, Foot Pedal Suction System	Reusable	SE
	Disposable Pump Cartridge, Disposable Pump Tubing, Disposable Control Button	Single Use	Pump Cartridge, Applicators	Single Use	
Labeling	Comply with 21 CFR part 801		Comply with 21 CFR part 801		SE

Compared with the reference device, the **Fluid Pump System** incorporates substantially equivalent device materials, design, configuration, packaging, sterilization process and intended use as those featured in the reference device **ERBEJET® 2 System**.

8. Performance Data

The following bench tests were performed:

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

Shelf-life testing and packaging integrity 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 and ISO 11607-1:2019: Packaging for terminally sterilized medical devices - Part 1:

Requirements for materials, sterile barrier systems and packaging systems and ISO 11607-2:2019: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes. One year aging test was performed to demonstrate the stability and support the results of the accelerated aging test.

Sterilization validation was carried out in accordance with ISO 11135:2014+A1:2018 "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-10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" issued on September 4, 2020.

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

- IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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

Software of **Fluid Pump System** had been confirmed according to FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "IEC 62304:2015 Medical device software - Software life cycle processes".

The results of all the performance testing demonstrated that the proposed device met the predetermined acceptance criteria and is substantial equivalence to the predicate device Single Use Electrosurgical Knife (K193601).

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 with Fluid Pump System** 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 (K193601)**.