December 1, 2021

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

Re: K210934
Trade/Device Name: Sphincterotome / short-wire compatible, Sterile Sphincterotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: October 27, 2021
Received: November 1, 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,

Je Hi An, 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)*
K210934

Device Name
Sphincterotome (Sphincterotome / short-wire compatible and Sterile Sphincterotome)

Indications for Use *(Describe)*
The Sphincterotome is intended to be used in the selective cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The device can also be used to inject contrast medium.

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.

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Section 5

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: **K210934**

1. Date of Preparation: 2021-12-01

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

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Email: RA.Micro-Tech@outlook.com

3. Identification of Proposed Device

Trade Name: Sphincterotome / short-wire compatible, Sterile Sphincterotome

Common Name: Sphincterotome

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/Reference Device

Predicate Device

510(k) Number: K013153

Product Name: Sphincterotome

Manufacturer: Boston Scientific Corporation (BSC)

Reference Devices:

510(k) Number: K955247

Product Name: Olympus KD Sphincterotome

Manufacturer: Olympus America, Inc.

Reference Devices:

510(k) Number: K061684

Product Name: Rotatable Sphincterotome

Manufacturer: Medi-Globe GmbH

5. Indications for Use

The device is intended to be used in the selective cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The device can also be used to inject contrast medium.

6. Device Description

The proposed device has two types: Sphincterotome / short-wire compatible and Sterile Sphincterotome. Sterile Sphincterotome commonly used in traditional Endoscopic Retrograde Cholangiopancreatography (Hereinafter referred to ERCP) surgery need to be used with a long guidewire, while Sphincterotome / short-wire compatible is compatible with short-wire techniques to compatible with a short guidewire to achieve rapid exchange between ERCP devices.

The proposed device consists of Cutting Wire, Outer Tube and Handle Assembly. It is used with the High Frequency Generator (Hereinafter referred to HF Generator) and the endoscopic procedures. The HF Generator supplies high frequency energy through the Cutting Wire of the proposed device to cut

the tissue at the appropriate power and voltage. The models with injection can inject contrast medium into the biliary ducts. The main materials of the proposed device include PTFE, ABS, SUS304.

The proposed device has 52 specifications, which mainly differ in cutting wire type, cutting wire length, preloaded guidewire length and with insulation tube or not.

The proposed device Sphincterotome is 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 1 year.

7. Comparison of Technological Characteristics

The proposed device Sphincterotome incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Sphincterotome.

Comparison between the proposed device and predicate device:

Item	Proposed Device **Sphincterotome**	Predicate Device **Sphincterotome (K013153)**	Remark
Product code	KNS	KNS	Same
Regulation No.	876.4300	876.4300	Same
Class	II	II	Same
Supplied in sterile	YES	YES	Same
Main material	PTFE, SUS304, ABS	Polymer materials, Stainless Steel	Different
Configuration	Consists of Cutting wire assembly, Outer tube assembly and Handle assembly	Consists of Cutting wire assembly, Outer tube assembly and Handle assembly	Same
Injection	Contrast medium	Contrast medium	Same
Cutting wire length	5mm, 20mm, 25mm, 30mm	20mm, 30mm	Different
Working length	2000mm	2000mm	Same
Tip length	5mm	5mm	Same
Tip Type	Cone Knife, Needle Knife	Cone Knife	Different

Item	Proposed Device **Sphincterotome**	Predicate Device **Sphincterotome** **(K013153)**	Remark
Cutting Wire Type	Single, Weave	Single	Different
Insulation Tube	With, Without	Without	Different
Compatible endoscopy working channel	≥3.2mm ≥2.8mm	≥2.8mm	Different
Compatible guidewire diameter	≤0.03 inch	≤ 0.035 inch	Same
Energy source	HF generator	HF generator	Same
Maximum rated accessory voltage	1200Vp (2400Vp-p)	750Vp (1500Vp-p)	Different
Indications for use	The Sphincterotome is intended to be used in the selective cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The device can also be used to inject contrast medium.	The Sphincterotome is indicated for use in the selective cannulation of the Common Bile Ducts (CBD) and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The Sphincterotome can also be used to inject contrast medium.	Same
Single use	Yes	Yes	Same
Packaging	1 Piece/Pouch	1 Piece/Pouch	Same
Shelf life	One year	Three years	Different
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	Same
Sterilization	EO Sterilized, SAL: 10^{-6}	EO Sterilized, SAL: 10^{-6}	Same
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	Same

Item	Proposed Device **Sphincterotome**	Predicate Device **Sphincterotome** **(K013153)**	Remark
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

The proposed device is similar in design and technological characteristics to the predicate device, although there are some differences, those differences have been compared with the reference device legally marketed in the U.S. market, and conduct the performance testing, the test results meet the requirement. Therefore, the difference between proposed device and predicated device is considered not to affect the Substantially Equivalency between the proposed and predicate devices concerning the safety and effectiveness.

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.

- Operation Testing
- Endoscope Compatibility Testing
- Head Preflexed Testing
- Conductivity Testing
- Connection Strength Testing
- Injection Luer Port Testing
- Infusion Patency Testing
- Energy Delivery and Cutting Testing
- Cutting Rate Testing
- Cannulation Performance Testing

- Endoscopy Visualization Testing

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. One-year aging test was 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 September 4, 2020.

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 **proposed device Sphincterotome** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared **predicate device Sphincterotome (K013153).**