DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 29, 2017

Micro-Tech (Nanjing) CO.,Ltd.
Becky Li
Quality and Regulatory Affairs Director
No. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
China

Re: K172309
Trade/Device Name: Endoscopic Ultrasound Aspiration Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODG, FCG
Dated: July 28, 2017
Received: July 31, 2017

Dear Becky Li:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172309

Device Name

Endoscopic Ultrasound Aspiration Needle

Indications for Use *(Describe)*

The Endoscopic Ultrasound Aspiration Needle is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope in adult patients only.

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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Tab 7

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: K172309

1. **Date of Preparation: 2017-09-29**

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: Becky Li

Position: Quality and Regulatory Affairs Director

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Email: In@micro-tech.com.cn

3. **Identification of Proposed Device**

Trade Name: Endoscopic Ultrasound Aspiration Needle

Common Name: Endoscopic ultrasound Needle

Regulatory Information

Classification Name: Endoscopes and Accessories

Classification: 2

Product Code: ODG & FCG

Regulation Number: 876.1500 & 876.1075

Review Panel: Gastroenterology/Urology

Intended Use Statement:

The Endoscopic Ultrasound Aspiration Needle is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope in adult patients only..

4. Identification of Predicate Device

Item	Predicate Device 1	Predicate Device 2	Predicate Device 3
510(k) Number	K070129	K083802	K160845
Product Name	Medi-Globe SonoTip II Ultrasound Needle System	Medi-Globe SonoTip II 25-gauge Ultrasound Needle System	Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device
Manufacturer	Medi-Globe Corporation	Medi-Globe Corporation	Boston Scientific Corporation

5. Indications for Use

The Endoscopic Ultrasound Aspiration Needle is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope in adult patients only..

6. Device Description

The proposed Endoscopic Ultrasound Aspiration Needle is a sterile single-use device, designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope.

It consists of three parts, Aspiration Needle, Syringe and Stopcock. The aspiration needle is offered with multiple types with different dimension, needle tip design and needle material. Syringe and stopcock are accessories to provide and control the vacuum suction to aspirate the sample.

There are 12 specifications, the difference is the diameter, material and tip design of needle.

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 Endoscopic Ultrasound Aspiration Needle of Micro-Tech (Nanjing) CO., Ltd. incorporates substantially equivalent materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices (K070129, K083802, K160845).

8. Performance Data

The proposed device **Endoscopic Ultrasound Aspiration Needle** 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 - 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 device specific guidance document was consulted in preparing this premarket submission, <Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology>. Performance testing such as Dimension Testing, Tensile Strength Testing, Needle Puncture Force Testing and etc, were performed.

The testing performed demonstrated that the proposed device meets the same performance requirements and is Substantially Equivalent (SE) to the currently cleared predicate devices (K070129, K083802, K160845).

9. Clinical Test Conclusion

Clinical Test is not applicable for the proposed device. No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Endoscopic Ultrasound Aspiration Needle** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared:

1) SonoTip II Ultrasound Needle System (K070129, Medi-Globe Corporation);

2) SonoTip II 25-gauge Ultrasound Needle System (K083802, Medi-Globe Corporation);

3) Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device (K160845, Boston Scientific Corporation).