December 6, 2021

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

Re: K212852
Trade/Device Name: Areus(TM) Adapt Endoscopic Ultrasound Aspiration Needle, Tridemt(TM) Endoscopic Ultrasound Aspiration Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODG, FCG
Dated: September 3, 2021
Received: September 7, 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)*
K212852

Device Name
Adapt Endoscopic Ultrasound Aspiration Needle

Indications for Use *(Describe)*
The device 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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510(k) 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: 2021-08-31**

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: Adapt Endoscopic Ultrasound Aspiration Needle

Common Name: Endoscopic Ultrasound Aspiration Needle

Regulatory Information

Classification Name: Endoscopic Ultrasound System, Gastroenterology-Urology & Biopsy Needle

Classification: II

Product Code: ODG, FCG

Regulation Number: 21 CFR§ 876.1500

Review Panel: Endoscope and Accessories

4. Identification of Predicate Device

Predicate Device

510(k) Number: K172309

Product Name: Endoscopic Ultrasound Aspiration Needle

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

5. Indications for Use

The device 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.

The Endoscopic Ultrasound Aspiration Needle consists of an Aspiration Needle and negative suction device. 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 Adapt Endoscopic Ultrasound Aspiration Needle incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate device **Endoscopic Ultrasound Aspiration Needle** cleared under K172309.

Table 7.1 Comparison to Predicate Devices

Item	Proposed Device Adapt Endoscopic Ultrasound Aspiration Needle	Predicate Device (K172309) Endoscopic Ultrasound Aspiration Needle	Remark
Product Code	ODG, FCG	ODG, FCG	Same
Regulation No.	876.1500	876.1500	Same

Section 5 510(k) Summary

Item	Proposed Device Adapt Endoscopic Ultrasound Aspiration Needle	Predicate Device (K172309) Endoscopic Ultrasound Aspiration Needle	Remark
Class	2	2	Same
Intended Use/Indications	The device is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope in adult patients only.	The device is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope in adult patients only.	Same
Single Use	Yes	Yes	Same
Configuration	Aspiration Needle and Negative suction device (including Stopcock and Syringe)	Aspiration Needle, Vacuum Syringe and Stopcock	Same
Compatible Endoscope Working Channel (mm)	≥2.8	≥2.8	Same
Needle Diameter	19G, 22G	19G, 22G, 25G	Similar
Needle Length out of Sheath (mm)	0~80	0~80	Same
Working Length (mm)	1375~1415	1375~1415	Same
Operation Principle	The device goes through the ultrasound endoscope to reach the target area, then the needle is pierced into the targeted lesions in the ultrasound image. The needle moves back and forth by operating the handle to sample tissue or cells by applying suction.	The device goes through the ultrasound endoscope to reach the target area, then the needle is pierced into the targeted lesions in the ultrasound image. The needle moves back and forth by operating the handle to sample tissue or cells by applying suction.	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	Two years	Same

Item	Proposed Device Adapt Endoscopic Ultrasound Aspiration Needle	Predicate Device (K172309) Endoscopic Ultrasound Aspiration Needle	Remark
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Same
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

Performance testing was conducted to demonstrate the essential performance of the proposed device **Adapt Endoscopic Ultrasound Aspiration Needle** and confirmed that the proposed device works as intended with the compatible devices.

The bench tests below were tested and evaluated as substantially equivalent to the predicate device.

- Smooth Actuation of Handle
- Leakage
- Ultrasound Visibility
- Puncture Force
- Stiffness
- Durability
- Stylet Removal Force
- Locking Force of Handle
- Tensile Strength

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. Two-years 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+A1:2018 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices".

The biocompatibility evaluation for the Adapt Endoscopic Ultrasound Aspiration Needle was conducted in accordance with ISO 10993-1: 2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" and FDA's biocompatibility 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,) the following tests were conducted:

The biocompatibility evaluation for the was conducted in accordance with ISO 10993-1: 2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" and FDA's biocompatibility 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,) the following tests were conducted:

- Cytotoxicity Test
- Sensitization Test
- Irritation Test
- Acute Systemic Toxicity Test
- Material Mediated Pyrogenicity Test
- Hemolysis Test

The results of all the performance testing demonstrated that the proposed device met the acceptance criteria and support substantial equivalence to the predicate device the predicate device **Endoscopic Ultrasound Aspiration Needle** cleared under **K172309**

9. Animal Study Conclusion

No animal study is included in this submission.

10. Clinical Test Conclusion

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 **Adapt 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 predicate device **Endoscopic Ultrasound Aspiration Needle** cleared under **K172309**.