February 21, 2026

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

Re: K251692
Trade/Device Name: Advanced Tissue Resection Device
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: FDI
Dated: January 22, 2026
Received: January 22, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SIVAKAMI VENKATACHALAM -S

for
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251692

Please provide the device trade name(s).

Advanced Tissue Resection Device

Please provide your Indications for Use below.

Advanced Tissue Resection Device has been designed to be used with an endoscope to electrosurgically resect mucosa within the digestive tract.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: K251692

1. Date of Preparation: 2026-01-22

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

#10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu 210032, China

Establishment Registration Number: 3004837686

Contact Person: Sally He

Position: Regional RA Manager

Tel: +86-25-58646378

Email: ra.mtus@mtmed.com

3. Identification of Proposed Device

Trade Name: Advanced Tissue Resection Device

Regulatory Information

Classification Name: Snare, Flexible

Product Code: FDI; Classification: 2

Regulation Number: 876.4300

Regulation Name: Endoscopic electrosurgical unit and accessories

Review Panel: Gastroenterology/Urology

4. Identification of Predicate/Reference Device

Predicate Device

510(k) Number: K955650

Product Name: Disposable Electrosurgical snare

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.

Reference Device

510(k) Number: K984358

Product Name: Disposable Distal Attachment

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.

5. Indications for Use

Advanced Tissue Resection Device has been designed to be used with an endoscope to electrosurgically resect mucosa within the digestive tract.

6. Device Description

The proposed device Advanced Tissue Resection Device is a sterile, single-use endoscopic device, intended to be used with endoscope to electrosurgically resect mucosa within the digestive tract. The proposed device has four specifications, the main differences of these specifications are working length and diameter of attaching distal end of endoscope. The proposed device 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 3 years.

7. Comparison of Technological Characteristics

The proposed device incorporates substantially equivalent's intended use, using environment, design, packaging fundamental technology, principles of operation, sterilization process, configuration, as those featured in the predicate device Disposable Electrosurgical Snare cleared under K955650.

ITEM	**Proposed Device** Advanced Tissue Resection Device	**Predicate Device** Disposable Electrosurgical Snare (K955650)	**Remark**
Product Code	FDI	FDI	SE
Regulation No.	21 CFR 876.4300	21 CFR 876.4300	SE
Class	II	II	SE
Indications for Use	Advanced Tissue Resection Device has been designed to be used with an endoscope to electrosurgically resect mucosa within the digestive tract	These instrument has been designed to be used with an Olympus endoscope to electrosurgically resect mucosa within digestive tract	SE
Configuration	The product is composed of a loop, a distal cap assembly, an outer tube, a conductive plug and a handle assembly	The product is composed of a loop, an outer tube, a conductive plug and a handle assembly	Similar
Energy source	HF generator	HF generator	SE
Electrical safety and Electromagnetic	Conform to: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Conform to: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	SE

	IEC 60601-2-18	IEC 60601-2-18	
Supplied Sterile	Sterile	Sterile	SE
Sterilization method	EO	EO	SE
Single Use	Yes	Yes	SE
Packaging	The Proposed Device is packaged in a sealed pouched	The Predicate Device is packaged in a sealed pouched	SE
Shelf Life	Three years	Three years	SE

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

The biocompatibility evaluation for proposed device was conducted in accordance with ISO 10993-1: 2018 "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:

a) Cytotoxicity
b) Sensitization
c) Irritation
d) Acute Systemic Toxicity
e) Material Mediated Pyrogenicity

The following performances were conducted and evaluated for the proposed device:

- Dimension Test
- Connection Force and Compatibility Endoscope Compatibility Test
- Resilience Test
- Pushability Test
- Cutting Test

- Connection Force Test
- Conductivity Test
- Visibility Test

Shelf-life testing and packaging integrity testing was conducted based on an accelerated aging test in accordance with ASTM F1980-21 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. Three-year accelerated aging test was performed to demonstrate the three-year stability in the shelf life.

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”.

Electromagnetic compatibility, electric safety, and thermal safety had been confirmed according to the following standards:
IEC 60601-1:2005/AMD2:2020 Medical Electrical Equipment - Part 1: Medical electrical equipment – general requirements for the basic safety and essential performance
IEC 60601-2-2:2017/AMD1:2023 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/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010/AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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, safety and performance testing, **Advanced Tissue Resection Device** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device cleared under K955650.