June 27, 2025

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

Re: K243388
Trade/Device Name: Disposable Distal Cap
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS
Dated: May 30, 2025
Received: May 30, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Shanil P. Haugen -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243388

Device Name
Disposable Distal Cap

Indications for Use *(Describe)*
Disposable Distal Cap is used with the endoscope and installed to the distal end of endoscope to keep appropriate endoscopic field of view.

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.

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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: K243388

1. Date of Preparation: 2025-05-22

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: Regional RA Manager

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3. Identification of Proposed Device

Trade Name: Disposable Distal Cap

Regulatory Information

Classification Name: Gastroscope And Accessories, Flexible/Rigid

Classification: 2

Product Code: FDS

Regulation Number: 876.1500

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K984358

Product Name: Disposable Distal Attachment

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.

5. Indications for Use

Disposable Distal Cap is used with the endoscope and installed to the distal end of endoscope to keep appropriate endoscopic field of view.

6. Device Description

Disposable Distal Cap is used with the endoscope and installed to the distal end of endoscope to keep appropriate endoscopic field of view. Disposable Distal Cap is a single structural product, a total of 3 types, and each type is divided into different specifications according to different inner diameter and the diameter of attaching endoscopic distal end. 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 one year.

7. Comparison of Technological Characteristics

The proposed device incorporates substantially equivalent device's intended use, using environment, design, packaging fundamental technology, principles of operation, manufacturing processes including sterilization process, configuration, as those featured in the predicate device Disposable Distal Attachment cleared under K984358.

ITEM	**Proposed Device** Disposable Distal Cap	**Predicate Device** Disposable Distal Attachment (K984358)	**Remark**
Product Code	FDS	FDS	SE
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	SE
Class	II	II	SE
Indications for Use	The Disposable Distal Cap is used with the endoscope and installed to the distal end of endoscope to keep appropriate endoscopic field of view	These instruments have been designed to be attached to the distal end of the endoscope to keep the suitable depth of endoscope's view field. Do not use these instruments for any purpose other than their intended uses.	SE
Configuration	Single structure, a component is a product	Single structure, a component is a product	SE
Supplied in Sterile	Sterile	Sterile	SE
Sterilization method	EO	EO	SE
Maximum diameter	11.35, 11.8, 12.4, 13.4, 14, 15, 15.7	11.35, 11.8, 12.4, 13.4, 14, 15, 15.7	SE
Compatibility	Compatible with different diameters of endoscopy	Compatible with different diameters of Olympus endoscopy	Similar
Single Use	Yes	Yes	SE

Packaging	One product is housed in a protective cover and packaged in a sealed pouched	One product is housed in a protective cover and packaged in a sealed pouched	SE
Shelf Life	One year	Three years	Similar
Patient-Contact Material	Silicone + Ink	TPES	Similar
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	SE
Sterilization	EO Sterilized, SAL: 10^{-6}	EO Sterilized, SAL: 10^{-6}	SE
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	SE

8. Performance Data

The biocompatibility evaluation for proposed device 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:

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

The following performances were conducted and evaluated for proposed device for all specifications:

- Dimension Test
- Endoscope Compatibility Test
- Endoscopic Field of view Test
- Connection Force Test

Side-by-side comparison testing have been conducted on the predicate device.

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".

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, **Disposable Distal Cap** 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 K984358.