



March 19, 2026

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

Re: K253139

Trade/Device Name: Disposable Distal Cap
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN
Dated: February 17, 2026
Received: February 17, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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

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.

K253139

?

Please provide the device trade name(s).

?

Disposable Distal Cap

Please provide your Indications for Use below.

?

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

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)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Mirco-Tech (Nanjing) Co., Ltd.
Applicant Address	No.10 Gaoke Third Rd Nanjing National Hi-Tech, Industrial Development Zone Nanjing Jiangsu 210032 China
Applicant Contact Telephone	+86-25-58646378
Applicant Contact	Ms. Sally He
Applicant Contact Email	ra.mtus@mtmed.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Disposable Distal Cap
Common Name	Endoscope and accessories
Classification Name	Choledochoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FBN

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K243388	Disposable Distal Cap	FDS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Disposable Distal Cap is used with the cholangioscope and installed to the distal end of cholangioscope to keep appropriate endoscopic field of view. Disposable Distal Cap is a single structural product, with 2 types, which are cylinder type and taper type. For each type, we have 1 specification, totally 2 specifications. 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 1 year.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The proposed device is designed to use with a choledochoscope, while the predicate device is designed to use with a gastrointestinal endoscope.

The indication of proposed device and predicate device has one difference. The predicate distal cap is intended to be used with various endoscope models (gastrosopes, colonoscopes) used for upper or lower gastrointestinal tract. The proposed distal cap is intended to be used with various cholangioscope models in the pancreatic or biliary systems. Although the indication is different, after the adequate benefit-risk analysis and taken the appropriate mitigation measures, such as appropriate performance testing, clinical literature and experience data, and labeling, the proposed device is as safe and effective as the predicate device(K243388).

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The proposed device incorporates the same sterilization method, material, chemical composition, principle of operation and substantial equivalence design as those featured in the predicate device Disposable Distal Cap cleared under K243388.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

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. The following tests are conducted:

- Dimension Test
- Endoscope Compatibility Test
- Endoscopic Field of view Test
- Connection Force Test
- Optical Performance Test
- Simulated Durability Testing
- Removal Testing
- Duodenoscope Compatibility Test

The biocompatibility evaluation was conducted in accordance with ISO 10993-1 "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.

Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The shelf life of proposed device is one year.

Sterilization validation was carried out in accordance with ISO 11135 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices".

No clinical tests were conducted and submitted in this 510(k) submission. Clinical literatures and clinical experience data are referenced to demonstrate the clinical safety and effectiveness of the proposed device.

The results of the tests mentioned demonstrated that the proposed device is as safe, as effective, and performs as well as the predicate device(K243388).