April 24, 2026

Mirco-Tech (Nanjing) Co., Ltd.
Sally He
Regional RA Manager
#10 Gaoke Third Rd.
Nanjing National Hi-Tech, Industrial Development Zone
Nanjing, Jiangsu 210032
China

Re: K253832
Trade/Device Name: Dilation Balloon Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: March 24, 2026
Received: March 24, 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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
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.	K253832

Please provide the device trade name(s).

Dilation Balloon Catheter

Please provide your Indications for Use below.

The Dilation Balloon Catheter is indicated for use in adults to endoscopically dilate strictures of the biliary tract.

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

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

510(k) #: K253832

510(k) Summary

Prepared on: 2026-03-24

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	Dilation Balloon Catheter
Common Name	Biliary catheter and accessories
Classification Name	Stents, Drains And Dilators For The Biliary Ducts
Regulation Number	876.5010
Product Code(s)	FGE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180418	Reliant(TM) Multistage Dilatation Balloon Catheter	FGE

Device Description Summary

21 CFR 807.92(a)(4)

The proposed device Dilation Balloon Catheter is a sterile, single-use endoscopic device. The proposed device is indicated for use in adults to endoscopically dilate strictures of the biliary tract. The proposed device has 9 specifications, and the main differences of these specifications are Balloon Length and Balloon diameter. The device reaches the expected position through the endoscopic channel, the balloon is inflated to the rated pressure to dilate the stenosis, and finally the device is withdrawn from the human body through the endoscopic channel. 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 one year.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Dilation Balloon Catheter is indicated for use in adults to endoscopically dilate strictures of the biliary tract.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed device is indicated for use in adults, the predicate device is indicated for use in adult and adolescent populations. The applicable patient population of the proposed device is included in that of the predicate device. The proposed device is indicated to endoscopically dilate strictures of the biliary tract, the predicate device is indicated endoscopically dilate strictures of the gastrointestinal tract. The applicable position of the proposed device is included in that of the predicate device.
Therefore, these differences are considered not to affect the substantially equivalency between proposed device and predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device incorporates the same principle of operation, packaging fundamental technology and sterilization as those featured in the predicate device cleared under K180418.
The material, chemical composition, intended use and configuration of proposed device is similar to predicate device, although there are some differences, those differences have been considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.
For a detailed comparison table,please refer to the attachment MTN-1017602 Substantially Equivalent Discussion are substantially equivalent.

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:
Balloon Appearance
Dimension
Balloon Inflation and Deflation Time
Balloon Burst Pressure
Tensile strength
Balloon Fatigue
Endoscopic Compatibility
Radiopacity Test
Patency
Leakproofness
Luer Connector
Balloon Diameter and Pressure Compliance

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.

The results of the tests mentioned demonstrated that the proposed device is as safe, as effective, and performs as well as the predicate device(K180418).