April 3, 2026

Micro-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: K254153
Trade/Device Name: Single-use Video Scope; PB Digital Controller
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN, FET
Dated: March 4, 2026
Received: March 4, 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.	K254153

Please provide the device trade name(s).

Single-use Video Scope;
PB Digital Controller

Please provide your Indications for Use below.

Single-use Video Scope:The Single-use Video Scope is used in combination with the PB Digital Controller, which is designed to provide imaging for the diagnosis and treatment application of endoscopic surgery process of pancreatic biliary system, and provide working channel for other diagnosis and treatment accessories.

PB Digital Controller: The PB Digital Controller can be used together with the endoscope to process the image collected by the endoscope and transmit it to the display.

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) #: K254153

510(k) Summary

Prepared on: 2026-03-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Micro-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	Single-use Video Scope; PB Digital Controller
Common Name	Endoscope and accessories
Classification Name	Choledochoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FBN, FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221784	Single-use Video Pancreaticobiliary Scope, PB Digital Controller	FBN
K142922	SpyGlass DS Access and Delivery Catheter	FBN

Device Description Summary

21 CFR 807.92(a)(4)

The Pancreaticobiliary Video System contains a PB Digital Controller and a Single-use Video Scope (hereinafter referred to as PB Scope). The Pancreaticobiliary Video System is an Endoscope device that can be used to process the image collected by the PB Scope and transmit it to the display.
The PB Digital Controller is reusable. The PB Digital Controller consists of a main controller and a power cord, the intended use of which is that PB Digital Controller can be used together with the endoscope (which includes both the "CDS Code series and the SVS Code series") to process the image collected by the endoscope and transmit it to the display.
The PB Scope is supplied sterile and for single use. The PB Scope has a maneuverable distal end and a flexible insertion portion. The camera and LED light source at the distal end can supply illumination and images. The PB Scope also has a working channel that can insert accessories.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Single-use Video Scope:The Single-use Video Scope is used in combination with the PB Digital Controller, which is designed to provide imaging for the diagnosis and treatment application of endoscopic surgery process of pancreatic biliary system, and provide working channel for other diagnosis and treatment accessories.

PB Digital Controller: The PB Digital Controller can be used together with the endoscope to process the image collected by the endoscope and transmit it to the display.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Single-use Video Scope: The intended use of proposed device is the same with predicate device,.

PB Digital Controller: Compared with Predicate Device PB Digital Controller (K221784), the compatible scopes range of proposed device has expanded from original "Single-Use Video Pancreaticobiliary Scope
(cleared under K221784)" to "Single-use Video Pancreaticobiliary Scope (CDS Code series,cleared under K221784)", "Visualized Access and Delivery Catheter (SVS Code series,in the process of 510k registration of K252492)" and "Single-use Video Scope"(CDS Code series,included in this 510(k) submission)",
based on this reason, the description of compatible scopes in Indication for Use of Proposed Device
PB Digital Controller has been adjusted accordingly, which has been changed from "Single-Use
Video Pancreaticobiliary Scope" to "endoscope", the intended use that to process the image
collected by the scope and transmit it to the display is not changed.

Therefore, the intended use of proposed device is the same with predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Single-use Video Scope:
The proposed device incorporates the same fundamental technology, Illumination source and sterilization packaging as those featured in the predicate device cleared under K221784.
The operating method, main structure, main materials, technological characteristics and shelf life 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.

PB Digital Controller:
The proposed device incorporates the same design, energy source, operation of principle and etc as those featured in the predicate device cleared under K221784.
The indications for compatible endoscope 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.

In conclusion, the Pancreaticobiliary Video System has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device Pancreaticobiliary Video System cleared under K221784.

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;
- Deflection Angle;
- Deflection reliability;
- Leakage;
- Compatibility Test with PB digital controller;
- Injection/Aspiration Patency;
- Connection Strength;
- Compatibility;
- Performance of Luer connector;
- Lubricating property;
- Field of View;
- Resolution;
- Image Intensity Uniformity;
- Depth of Field;
- Color Performance;
- Signal-to-noise ratio (SNR);
- Dynamic Range;
- Geometric Distortion;
- Performance of Backflow Prevention;
- Direction of View;
- Photobiological Safety

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".

Electrical performance was performed in accordance with the current version of IEC 60601-1:"Medical electrical equipment - Part 1: General requirements for basic safety and essential performance", IEC 60601-2-18 "Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment", IEC 60601-1-2:"Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests".

Not Applicable,no clinical study is included in this submission.

The results of the performance testing supported substantial equivalence and the proposed device is as safe, as effective, and performs as well as the predicate device.