April 24, 2026

Micro-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: K252492
Trade/Device Name: Visualized Access and Delivery Catheter; PB Digital Controller
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: SHU, FET
Dated: March 27, 2026
Received: March 27, 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, PhD
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.	K252492

Please provide the device trade name(s).

Visualized Access and Delivery Catheter
PB Digital Controller

Please provide your Indications for Use below.

Visualized Access and Delivery Catheter:
The Visualized Access and Delivery Catheter have been designed to be used with the PB Digital Controller, which is designed to provide imaging for the diagnosis and treatment application of endoscopic surgery process of vermiform appendix, and provide working channel for other diagnosis and treatment accessories.
The Visualized Access and Delivery Catheter is to be used with a colonoscope for appendicitis diagnosis and treatment procedures under direct visualization in adults, adolescents, and children.

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

510k Summary (K252492/S001)

Date of Preparation: 2026-04-22

Contact Details

Applicant Name: Micro-Tech (Nanjing) Co., Ltd.
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Legally Marketed Predicate Devices

510(k) Number: K221784
Predicate Trade Name: Single-use Video Pancreaticobiliary Scope, PB Digital Controller
Product Code: FBN

Device Name

Device Trade Name: Visualized Access and Delivery Catheter; PB Digital Controller
Common Name: Endoscope and accessories
Classification Name: Appendiceal scope and Accessories, Flexible
Regulation Number: 876.1500
Product Codes: SHU and FET

Device Description Summary

The Appendiceal Video System contains a PB Digital Controller and a Visualized Access and Delivery Catheter (hereinafter referred to as Catheter). The Catheter is supplied sterile and for single use.
The Appendiceal Video System is an Endoscope device that can be used to process the image collected by the Catheter 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 "Single-use Video Pancreaticobiliary Scope" and "Visualized Access and Delivery Catheter") to process the image collected by the endoscope and transmit it to the display.

Intended Use/ Indications for Use

Visualized Access and Delivery Catheter:

The Visualized Access and Delivery Catheter have been designed to be used with the PB Digital Controller, which is designed to provide imaging for the diagnosis and treatment application of endoscopic surgery process of vermiform appendix, and provide working channel for other diagnosis and treatment accessories.

The Visualized Access and Delivery Catheter is to be used with a colonoscope for appendicitis diagnosis and treatment procedures under direct visualization in adults, adolescents, and children.

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

Single-Use Video Pancreaticobiliary Scope: The intended use is that it has been designed to be used with the PB digital controller, which is designed to provide imaging for the diagnosis and treatment application of endoscopic surgery process within the gastrointestinal tract and provide working channel for other diagnosis and treatment accessories.
Compared with the predicate device, the appendix system is the target place in the indication for use and anatomic sites of the proposed 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 both "Single-Use Video Pancreaticobiliary Scope (cleared under K221784)" and "Visualized Access and Delivery Catheter (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 "appendiceal endoscope", the intended use that to process the image collected by the scope and transmit it to the display is not changed.

Therefore, the difference do not constitute a new intended use.

Technological Comparison

The proposed device has the same technological characteristics to the predicate device in design, main material, fundamental technology, principle of operation, energy source, sterilization packaging, shelf-life and manufacturing process.
Based on the indications for use, technological characteristics, and safety and performance testing, the Appendiceal 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 (K221784).

Non-Clinical and/or Clinical Tests Summary & Conclusions

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.
- ➢ Field of View;
- ➢ Resolution;
- ➢ Image Intensity Uniformity;
- ➢ Depth of Field;
- ➢ Color Performance;
- ➢ Signal-to-noise ratio (SNR);
- ➢ Dynamic Range;
- ➢ Geometric Distortion;
- ➢ Photobiological Safety
- ➢ Performance of Backflow Prevention

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 two years.

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".

No clinical tests are included 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 performance testing and clinical literature supported substantial equivalence and the proposed device is as safe, as effective, and performs as well as the predicate device K221784.