February 16, 2023

Micro-Tech (Nanjing) Co., Ltd
Sally He
RA Engineer
No. 10 Gaoke Third Road
Nanjing National Hi-tech Industrial Development Zone
Nanjing, Jiangsu 210032
CHINA

Re: K221784
Trade/Device Name: Single-use Video Pancreaticobiliary Scope, PB Digital Controller
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBN, NTN, KQM
Dated: August 26, 2022
Received: January 17, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221784

Device Name
Pancreaticobiliary Video System

Indications for Use *(Describe)*

The Pancreaticobiliary Video System consists of PB Digital Controller and Single-use Video Pancreaticobiliary Scope.

The Single-use Video Pancreaticobiliary 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.

The PB Digital Controller can be used together with the Single-use Video Pancreaticobiliary Scope of Micro-Tech to process the image collected by the scope and transmit it to the display.

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.

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510K 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: **K221784**

1. Date of Preparation: 2023-02-08

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

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3. Identification of Proposed Device

Trade Name: Single-use Video Pancreaticobiliary Scope, PB Digital Controller

Common Name: Pancreaticobiliary Video System

Regulatory Information

Device Classification Name: Endoscope and accessories

Classification regulation: 876.1500(FBN, NTN, FET), 874.4160(KQM)

Class and Review Panel: Class II, Gastroenterology/Urology (FBN, NTN, FET)

Class I, General and plastic surgery (KQM)

Product code: FBN, KQM, NTN, FET

4. Identification of Predicate Device and Reference Device

Predicate Device:

510(k) Number: K142922

Product Name: SpyGlass DS Direct Visualization System

Manufacturer: Boston Scientific Corporation.

Reference Device:

510(k) Number: K200483

Product Name: SpyGlass Discover Digital System

Manufacturer: Boston Scientific Corporation.

5. Indications for Use

The Pancreaticobiliary Video System consists of PB Digital Controller and Single-use Video Pancreaticobiliary Scope.

The Single-use Video Pancreaticobiliary 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.

The PB Digital Controller can be used together with the Single-use Video Pancreaticobiliary Scope of Micro-Tech to process the image collected by the scope and transmit it to the display.

6. Device Description

Pancreaticobiliary Video System consists of:

Single-Use Video Pancreaticobiliary Scope:

- CDS11001
- CDS11002
- CDS11003
- CDS11004
- CDS11005

- CDS22001
- CDS22002
- CDS22003
- CDS22004
- CDS22005

PB Digital Controller:

- BS-W-100

The Single-Use Video Pancreaticobiliary Scope is a sterile single use flexible scope and PB Digital Controller is a reusable device.

The Single-Use Video Pancreaticobiliary Scope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Insertion port
- Suction port
- Camera at the distal tip and LED light source in the handle of the pancreaticobiliary scope

  The light emitted by the cold light source located in the handle is transmitted to the distal end of the pancreaticobiliary scope through the glass fiber, and irradiates the human tissue from the distal end. CMOS and glass fiber are located at the same position at the distal end. CMOS transmits the collected image information to the PB Digital Controller through cable, and the PB Digital Controller displays the image on the display after processing.

  CMOS and optical components are identical for all specifications of products.
- Working channel port
- Lever which can lock the control

The Single-Use Video Pancreaticobiliary Scope have different size as follows:

- Maximum insertion portion width
- Effective working length
- Minimum accessories channel width

The PB Digital Controller has the following physical and performance characteristics:

- Displays the image from The Single-Use Video Pancreaticobiliary Scope on the screen
- Can record screenshots or video of image from the Single-Use Video Pancreaticobiliary Scope
- Can connect to an external monitor
- Reusable device

7. Comparison of Technological Characteristics

The **Pancreaticobiliary Video System** substantially equivalent device materials, design, configuration, sterilization process and intended use as those featured in the predicate device SpyGlass DS Direct Visualization System (K142922) and SpyGlass Discover Digital System (K200483).

Comparison to Predicate Device and Reference Device:

Table 1 Substantial Equivalence Comparison between Proposed Single-Use Video Pancreaticobiliary Scope and Predicate/Reference Device

Characteristics	**Proposed Device**	**Predicated Device**	**Reference Device**	**Remark**
	Single-Use Video Pancreaticobiliary Scope	**SpyGlass DS Access and Delivery Catheter (K142922)**	**SpyGlass Discover Digital Catheter（K200483）**	
Product Code	FBN, KQM, NTN	FBN, KQM, NTN	FBM,KQM, NTN	Same
Class	II	II	II	Same
Regulation Description	Pancreaticobiliary Scope (flexible or rigid) and accessories	Pancreaticobiliary Scope (flexible or rigid) and accessories	Pancreaticobiliary Scope (flexible or rigid) and accessories	Same
Regulation number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Same
Illumination Source	LED	LED	LED	Same
Indication for Use	The Single-use Video Pancreaticobiliary 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	Intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.	The Spyglass Discover Digital Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary	Similar

Characteristics	Proposed Device Single-Use Video Pancreaticobiliary Scope	Predicated Device SpyGlass DS Access and Delivery Catheter (K142922)	Reference Device SpyGlass Discover Digital Catheter（K200483）	Remark
	provide working channel for other diagnosis and treatment accessories.		system including the hepatic ducts.	
Operating method	ERCP, PTC	ERCP	LCBDE, PTC, Open Surgical procedure	Similar
Working length	2200mm 800mm 650mm 600mm 400mm	2140mm	650mm	Similar
Images Sensor	CMOS	CMOS	CMOS	Same
Reusability	Single-Use	Single-Use	Single-Use	Same
Sterile	Yes	Yes	Yes	Same
Anatomic sites	Pancreatic biliary system	Pancreatic biliary system	Pancreatic biliary system	Same
Target population	Adults	Adults	Adults	Same
Rx-only	Yes	Yes	Yes	Same
Tip Diameter	3.7mm 3.1mm	3.5mm	3.5mm	Similar
Shaft Diameter	3.9mm 3.2mm	3.6mm	3.6mm	Similar
Working Channel Diameter	2.0mm 1.2mm	1.2mm	1.2mm	Similar

Characteristics	Proposed Device Single-Use Video Pancreaticobiliary Scope	Predicated Device SpyGlass DS Access and Delivery Catheter (K142922)	Reference Device SpyGlass Discover Digital Catheter（K200483）	Remark
Minimum Duodenoscope Working channel	4.2mm 3.7mm	4.2mm	Not used through duodenoscope	Similar
Minimum Sheath Working Channel	4.0mm 3.3mm	Not used through sheath	3.6mm	Similar
Deflection	4way ≥45 °	4way ≥30 °	4way ≥30 °	Greater
Direction of View	0	0	0	Same
Field of view	120	120	120	Same
Resolution	12.7lines/mm @5mm object distance	7.13 lines/mm @5mm object distance	Unknown	Greater
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Comply with ISO 10993-1	Same
Shelf Life	2 Years	2 Years	2 Years	Same
Electrical Performance	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Same

Table 2 Substantial Equivalence Comparison between Proposed PB Digital Controller and Predicate/Reference Device

Characteristics	Proposed Device PB Digital Controller	Predicated Device SpyGlass DS Digital Controller(K142922)	Reference Device SpyGlass Discover Digital Controller(K200483)	Remark
Product Code	FBN,FET	FBN	FBN	PB Digital Controller is

Characteristics	Proposed Device PB Digital Controller	Predicated Device SpyGlass DS Digital Controller(K142922)	Reference Device SpyGlass Discover Digital Controller(K200483)	Remark
				a video processor regulated under FET.
Class	II	II	II	Same
Regulation Description	Pancreaticobiliary Scope (flexible or rigid) and accessories Endoscopic Video Imaging System/Component, Gastroenterology-Urology	Pancreaticobiliary Scope (flexible or rigid) and accessories	Pancreaticobiliary Scope (flexible or rigid) and accessories	PB Digital Controller is one component of endoscopic Video Imaging System
Regulation number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Same
Indication for Use	The PB Digital Controller can be used together with the Single-use Video Pancreaticobiliary Scope of Micro-Tech to process the image collected by the scope and transmit it to the display.	The SpyGlass DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.	The Spyglass Discover Digital Controller is intended to provide illumination and receive, process, and output images from the Spyglass Discover Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.	Similar
Characteristics	Proposed Device PB Digital Controller	Predicated Device SpyGlass DS Digital Controller(K142922)	Reference Device SpyGlass Discover Digital Controller(K200483)	Remark
Video Formats	PAL and NTSC	PAL and NTSC	PAL and NTSC	Same
Video Outputs	DVI, CVBS	S-Video, VGA，DVI	S-Video, VGA，DVI	Similar

Characteristics	Proposed Device PB Digital Controller	Predicated Device SpyGlass DS Digital Controller(K142922)	Reference Device SpyGlass Discover Digital Controller(K200483)	Remark
White Balancing	Automatic	Automatic	Automatic	Same
Brightness Control	5 settings	5 settings	5 settings	Same
Separate monitor	Yes	Yes	Yes	Same
Energy used/Power source	Yes	Yes	Yes	Same
Reusability	Reusable	Reusable	Reusable	Same
Rx-only	Yes	Yes	Yes	Same
Shelf Life	5 Years	5 Years	5 Years	Same
Electrical Performance	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Comply with ANSI AAMI ES60601-1 IEC60601-1-2 IEC 60601-2-18	Same

8. Performance Data

Performance testing was conducted to demonstrate the essential performance of the proposed device **Pancreaticobiliary Video System** and confirmed that the proposed device works as intended with the compatible devices.

The bench tests below were tested and evaluated as substantially equivalent to the predicate device.

- Diameter
- Working length
- Working channel diameter
- Liquid injection and aspiration
- Field of view
- Resolution
- Articulation direction

- Articulation angle
- Surface and edges
- Leakage
- Attachment to duodenoscope reliability
- Duodenoscope compatibility
- Irrigation pump compatibility
- Accessory compatibility

Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. A one-year aging test was performed to demonstrate longer stability and support the results of the accelerated aging test.

Sterilization validation was carried out in accordance with ISO 11135:2014 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization Processes for Medical Devices”

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of international Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Electrical performance was performed in accordance with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”, IEC 60601-2-18:2009 “Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment”, IEC 60601-1-2:2014 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”

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, and safety and performance testing, 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 SpyGlass DS Direct Visualization System under K142922 and reference device SpyGlass Discover Digital System under K200483, the subject device is as safe, as effective, and performs as well as the predicate/reference device.