March 14, 2025

Shenzhen Sanping Image Technology Co., Ltd.
Vincent Pan
General Manager
Room 203, No.634, Shajing Road,
Buchong Community, Shajing Street, Bao'an District
Shenzhen, Guangdong 518104
China

Re: K242010
Trade/Device Name: Bronchoscope System, The Single-use Bronchoscope (Single-use Bronchoscope: SP-Y-ZQGJ2.8, SP-Y-ZQGJ3.8, SP-Y-ZQGJ4.2, SP-Y-ZQGJ4.8, SP-Y-ZQGJ5.2, SP-Y-ZQGJ5.8; Electronic Endoscope Imaging Processor: SP-TXCLQ12.1)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: July 10, 2024
Received: July 10, 2024

Dear Pan Vincent:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242010

Device Name

Bronchoscope System、The Single-use Bronchoscope (Single-use Bronchoscope：SP-Y-ZQGJ2.8、SP-Y-ZQGJ3.8、SP-Y-ZQGJ4.2、SP-Y-ZQGJ4.8、SP-Y-ZQGJ5.2、SP-Y-ZQGJ5.8; Electronic Endoscope Imaging Processor：SP-TXCLQ12.1)

Indications for Use *(Describe)*

The Single-use Bronchoscopes have been designed to be used with the Electronic Endoscope Imaging Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.
The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a single-use device designed for use in adults.

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.

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510(k) Summary

1. Sponsor Identification:

- Company Name: Shenzhen Sanping Image Technology Co., Ltd.
- Address: Room 203, No.634, Shajing Road, Buchong Community, Shajing Street, Bao'an District, Shenzhen, China
- Phone: +86-755-23223975
- Fax: +86-755-23223975
- Contact Person (Title): Vincent Pan (General Manager)
- E-mail：99020278@qq.com
- Date of Preparation: December 26, 2024

2. Name of the Device:

Trade Name	Bronchoscope System、The Single-use Bronchoscope	**Model Number/Name**	Single-use Bronchoscope： SP-Y-ZQGJ2.8、 SP-Y-ZQGJ3.8、 SP-Y-ZQGJ4.2、 SP-Y-ZQGJ4.8、 SP-Y-ZQGJ5.2、 SP-Y-ZQGJ5.8
		Model Number/Name	Electronic Endoscope Imaging Processor：SP-TXCLQ12.1

3. Common Name and Classification:

- Device Classification Name: Bronchoscope (Flexible Or Rigid)
- Classification Product Code: EOQ

- Regulation Number: 21 CFR 874.4680
- Class: 2
- Review Panel: Ear Nose & Throat
- Trade/Proprietary Name: The Single-use Bronchoscopes、Bronchoscope System
- Common Name: Bronchoscope (flexible or rigid) and accessories

4. Predicate Device Information1:

- 510(k) Number: K231107
- Device Classification Name: Bronchoscope (Flexible Or Rigid)
- Sponsor: Hunan Endoso Life Technology Co., Ltd.
- Classification Product Code: EOQ
- Regulation Number: 21 CFR 874.4680
- Class: 2
- Review Panel: Ear Nose & Throat
- Trade/Proprietary Name: Single-use Bronchoscope, Monitor for Single-Use Endoscopy, Bronchoscope System
- Common Name: Bronchoscope (flexible or rigid) and accessories

5. Predicate Device Information2:

- 510(k) Number: K191828
- Device Classification Name: Bronchoscope (Flexible Or Rigid)
- Sponsor: Hunan Vathin Medical Instrument Co., Ltd.
- Classification Product Code: EOQ
- Regulation Number: 21 CFR 874.4680
- Class: 2
- Review Panel: Ear Nose & Throat
- Trade/Proprietary Name: Vathin® Video Bronchoscope System
- Common Name: Bronchoscope (flexible or rigid) and accessories

6. Device Description

The Single-use Bronchoscope is a sterile single used flexible bronchoscope. The Electronic Endoscope Imaging Processor is a reusable monitor.

The light emitted by the LED cold light source at the distal tip of the Single-use Bronchoscope is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is captured by the CMOS image sensor. The CMOS acquisition image is controlled by the CMOS drive circuit, and the RGB video signal is output of the Electronic Endoscope Imaging Processor via the encoding circuit. The Electronic Endoscope Imaging Processor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the monitor. The Electronic Endoscope Imaging Processor also controls the brightness of the LEDs on the endoscope.

The optical components and their arrangement at the distal tip for all models of the Single-use Bronchoscope are identical.

The Single-use Bronchoscope is single-use medical devices that are sterilized with ethylene oxide and intended for use in adults. This product is accompanied by an electronic endoscopic image processor, which supports the use of medical monitors. The electronic bronchoscope system is used for endoscopic diagnosis or treatment, and the processor collects, processes, stores, and transmits images of the human body cavity to the monitor.

7. Indications for Use

The Single-use Bronchoscopes have been designed to be used with the Electronic Endoscope Imaging Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a single-use device designed for use in adults.

8. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device 1 K231107	Predicate Device 2 K191828	Judgment
Company Name	Shenzhen Sanping Image Technology Co., Ltd.	Hunan Endoso Life Technology Co., Ltd.	Hunan Endoso Life Technology Co., Ltd.	/
Model	Single-use Bronchoscope: SP-Y-ZQGJ2.8、SP-Y-ZQGJ3.8、SP-Y-ZQGJ4.2、SP-Y-ZQGJ4.8、SP-Y-ZQGJ5.2、SP-Y-ZQGJ5.8 Electronic Endoscope Imaging Processor：SP-TXCLQ12.1	Single-use Bronchoscope: BC12-1, BC12-2, BC20-1, BC20-2, BC22-1, BC22-2, BC22-3, BC28-1, BC28-2, BC28-3 Monitor for Single-Use Endoscopy: P1-A, P1-B, P1-C, P1-D, P1-E, P2-A, P2-B, P2-C, P2-D, P2-E	Vathin®H-SteriScope™ Single-use flexible Video Bronchoscope BCV1-01 BCV1-02 BCV1-C1 BCV1-C2 BCV1-H1 BCV1-H2 BCV1-K1 BCV1-K2 BCV1-M1 BCV1-M2 BCV1-O1 BCV1-O2 BCV1-S1 BCV1-S2 BCV1-U1 BCV1-U2 BCV1-W1 BCV1-W2 Vathin®VisionCenter™ I Digital Video Processor DVP-A1	/
Device Name	Bronchoscope System	Bronchoscope System	Vathin® Video Bronchoscope System	/
Classification Product Code	EOQ	EOQ	EOQ	SE
Regulation	874.4680	874.4680	874.4680	SE
Classification Name	Bronchoscope (Flexible Or Rigid)	Bronchoscope (Flexible Or Rigid)	Bronchoscope (Flexible Or Rigid)	SE

Review Panel	Ear Nose & Throat	Ear Nose & Throat	Ear Nose & Throat	SE
Class	2	2	2	SE
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	SE
Anatomic sites	airways and tracheobronchial tree	airways and tracheobronchial tree	airways and tracheobronchial tree	SE
Target Population	Adults	Adults	Adults	SE
Where used	Hospital	Hospital	Hospital	SE

Working place/User	Use in a hospital environment by trained surgical physicians who are familiar with endoscopic procedures.	Use in a hospital environment by trained surgical physicians who are familiar with endoscopic procedures.	Use in a hospital environment by trained surgical physicians who are familiar with endoscopic procedures.	SE
Technology	The Single-use bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. Anatomical images are transmitted to the user by the Monitor for Single-Use Endoscopy with a CMOS chip at the distal end of the endoscope and the images showing on the monitor.	The Single-use bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. Anatomical images are transmitted to the user by the Monitor for Single-Use Endoscopy with a CMOS chip at the distal end of the endoscope and the images showing on the monitor.	The Single-use bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. Anatomical images are transmitted to the user by the Monitor for Single-Use Endoscopy with a CMOS chip at the distal end of the endoscope and the images showing on the monitor.	SE

Intended Use	The Single-use Bronchoscopes have been designed to be used with the Electronic Endoscope Imaging Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a single-use device designed for use in adults.	The Single-use Bronchoscopes have been designed to be used with the Monitor for Single-Use Endoscopy, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a disposable device designed for use in adults.	The Vathin®H-SteriScopeTM I Single-use flexible Video Bronchoscope have been designed to be used with the Vathin®VisionCenterTM I Digital Video Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Vathin® Video Bronchoscope System is for use in a hospital environment.	SE

Table 2 Safety factor & Performance Comparison

Safety factor & Performance	Proposed Device	Predicate Device1	Predicate Device2	Judgment
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Compliance with IEC 60601-1	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Usability Engineering	Compliance with IEC 62366-1	Compliance with IEC 62366-1	Compliance with IEC 62366-1	SE
Biocompatiblity	Compliance with ISO 10993-1	Compliance with ISO 10993-1	Compliance with ISO 10993-1	SE

Safety factor & Performance	Proposed Device	Predicate Device1	Predicate Device2	Judgment
Connect to devices	Monitor	Monitor	Monitor	SE
Type of Imager	CMOS	CMOS	CMOS	SE
Light Source	Internal LED	Internal LED	Internal LED	SE
Direction of View (°)	forward	forward	forward	SE
Working Length (mm)	650	600mm	600/700mm	Note 1
Depth of Field (mm)	3 - 50	3 - 50	3mm~30mm	SE
Type of Scope	Flexible	Flexible	Flexible	SE
Distal end outer diameter	⩽2.9mm (8.7 Fr)	⩽2.9mm (8.7 Fr)	⩽3.1mm (9.3 Fr)	SE
Deflection Angle	Up & Down 180°, tolerance ±10%	Up & Down 180°, tolerance ±10%	Up: 210 Down: 210	SE
Distal end diameter(mm)	3.00/4.05/4.40/4.80/5.20/6.10	/	2.2/3.2/4.1/4.7/4.9/5.2/5.8/6.0/6.2	Note 2
Maximum insertion portion width(mm)	3.20/4.25/4.55/5.40/5.70/6.35	/	2.2/3.2/4.1/4.7/4.9/5.2/5.8/6.0/6.2	Note 2
Minimum insertion channel width(mm)	1.20/1.60/2.20/2.60/3.00/3.20	/	0/1.2/1.7/2.0/2.2/2.4/2.8/3.0/3.2	Note 2
General material type of main patient-contact	Compliance with ISO10993 - 1	Compliance with ISO10993 - 1	Compliance with ISO10993 - 1	SE
General material type of main patient-contact part	Pebax, polyamide, Stainless Steel, Epoxy glue, glass, Polycarbonate, PTFE, PET	Pebax, polyamide, Stainless Steel, Epoxy glue, glass, Polycarbonate, PTFE, PET	Pebax, PTFE, LCP, TPU, Fluoro elastomers, Epoxy glue, glass	SE

Safety factor & Performance	Proposed Device	Predicate Device1	Predicate Device2	Judgment
Duration and type of contact	"Surface - Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	"Surface - Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	"Surface - Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	SE
Number of Users	Single-Use	Single-Use	Single-Use	SE
Sterilization	EO Sterilized, SAL 10^{-6}	EO Sterilized, SAL 10^{-6}	EO Sterilized, SAL 10^{-6}	SE

8.1 Review of Differences：

Note1:

There is slight difference in the working length as compared to the predicate. However, the working length of the device is utilized by many similar devices in clinical practice. Therefore, this variance does not raise different questions of its safety and effectiveness.

Note 2:

The difference lies in the mechanical specifications, there may be slight size differences within the same specification and all within the tolerance range. All the performance was tested, and the results met the standard requirements, these differences will not raise any issues in safety and effectiveness.

8.2 Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows：

A series of non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

1) Electrical safety

IEC6060-1:2005+A1:2012+A2:2020, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

2) Electromagnetic compatibility (EMC)

IEC 60601-1-2:2014 + A1:2020 / ANSI AAMI IEC 60601-1-2:2014 + A1:2021], Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests.

IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

3) Basic Safety and Essential Performance

IEC 60601-1-6:2010 + A1:2020 + A2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

4) Photobiological safety

IEC 62471:2006, Medical electrical equipment, Photobiological safety of lamps and lamp systems.

5) Biocompatibility testing

ISO 10993-1:2018 Biological evaluation of medical devices-Parts 1: Evaluation and testing.

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021 Biological evaluation of medical devices - Parts 10: Tests for skin sensitization

ISO 10993-11:2017 Biological evaluation of medical devices, Part 11: Tests for

systemic toxicity

ISO 10993-23:2021 Biological evaluation of medical devices-Parts 10: Tests for irritation

6) Sterilization and Shelf Life & Packaging testing

ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.

ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

ISO 10993-7: 2019, Biological evaluation of medical devices: Part 7-Ehylene oxide Sterilization Residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019).

The system performance tests were performed including validation of up/down deflection、repeated flexing, water supply system, sealing performance, normal working condition, field of View, direction of view (DOV)、geometric distortion, Signal-To-Noise Ratio, Image Intensity Uniformity (IIU)、and color performance.

All the test results demonstrate Bronchoscope System meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate device.

9. Clinical Tests Performed

No clinical test data was used to support the decision of substantial equivalence.

10. Conclusion

The subject devices have all features of the predicate devices. The few differences were evaluated and do not affect the safety and effectiveness of the subject devices compared to the predicate.

Thus, the subject devices are substantially equivalent to the predicate devices.