November 14, 2023

Scivita Medical Technology Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120, China

Re: K231521
Trade/Device Name: Broncho Videoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: October 11, 2023
Received: October 11, 2023

Dear Diana Hong:

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.

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

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)*

K231521

Device Name

Broncho Videoscope System

Indications for Use *(Describe)*

The Broncho videoscope system is designed to be used for endoscopic diagnosis and therapies within the respiratory system such as trachea, bronchi, and lungs. The Broncho videoscope System is for use in a hospital environment.

This Full HD Visualization Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the electronic endoscopes, displaying the images on its LCD display and/or external monitor within the field of view from the body cavity.

This Single-use Broncho Videoscope is intended to use in conjunction with endoscopic image processor to provide images through the video monitor for observation, diagnosis, photography and treatment of the respiratory system such as trachea, bronchi, and lungs.

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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K231521

1. Date of Preparation: 11/10/2023

2. Sponsor Identification

Scivita Medical Technology Co., Ltd.
No. 2, Qingqiu Street, Suzhou Industrial Park, 215000 Suzhou, Jiangsu Prov., P.R.CHINA.

Establishment Registration Number: 3020746799

Contact Person: Ruqin Wu
Position: Quality Manager
Tel: +86-512-81877788
Fax: +86-512-85187285
Email: wuruqin@scivitamedical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Subject Device

Trade Name: Broncho Videoscope System
Common Name: Bronchoscope System

Regulatory Information
Classification Name: Bronchoscope (Flexible or Rigid);
Classification: II;
Product Code: EOQ;
Regulation Number: 21 CFR 874.4680;
Review Panel: Ear Nose & Throat;

Indication for use:
The Broncho videoscope system is designed to be used for endoscopic diagnosis and therapies within the respiratory system such as trachea, bronchi, and lungs. The Broncho videoscope System is for use in a hospital environment.

This Full HD Visualization Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the electronic endoscopes, displaying the images on its LCD display and/or external monitor within the field of view from the body cavity.

This Single-use Broncho Videoscope is intended to use in conjunction with endoscopic image processor to provide images through the video monitor for observation, diagnosis, photography and treatment of the respiratory system such as trachea, bronchi, and lungs.

Device Description:
The subject device, Broncho Videoscope System is consisting of a Single-use Broncho Videoscope and a Full HD Visualization Endoscopic Image Processor. The subject device has been designed to be used for endoscopic diagnosis and therapies within the respiratory system such as trachea, bronchi, and lungs.

System Configuration

System name	Component name	Model
Broncho Videoscope System	Single-use Broncho Videoscope	SBV-1A-B, SBV-1A-P, SBV-1B-B, SBV-1B-P, SBV-1C-B, SBV-1C-P
	Full HD Visualization Endoscopic Image Processor	HDVS-S300A, HDVS-S300B, HDVS-S300C, HDVS-S300D

The Single-use Broncho Videoscope, which has been cleared in K210379, is a single use device. It is intended to use in conjunction with Full HD Visualization Endoscopic Image Processor to provide

images through the video monitor for observation, diagnosis, photography and treatment of the respiratory system such as trachea, bronchi and lungs. The Single-use Broncho Videoscope has six modes, which are available in three kinds of outer diameter of insertion section (Φ2.8mm, Φ4.2mm and Φ5.6mm), one working length (600mm) and two different material of the insertion section (Nylon and PEEK). All these six models are included in K210379.

The single-use Broncho Videoscope is a single-channel endoscope. There is only one working channel is in the distal end of the endoscope, and it bifurcates to two channels leading to the irrigation valve and suction section.

The Single-use Broncho Videoscope is sterilized by Ethylene Oxide (EO) Gas to achieve a SAL of 10^{-6} and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of three years.

The Full HD Visualization Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the Single-use Broncho Videoscope, displaying the images on its LCD display and/or external monitor within the field of view from the body cavity. The Full HD Visualization Endoscopic Image Processor has four models, which are different in image adjustment functions.

5. Identification of Predicate Device

510(k) Number: K210379

Product Name: Broncho Videoscope System

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to demonstrate substantial equivalence (SE) to the predicate. The test results demonstrated that the subject device complies with the following standards:

- ISO 10993-7:2008 Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals
- 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
- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 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 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems

- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88/F88M -21, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological Characteristics

Table 1. General Comparison

ITEM	Subject Device K231521	Predicate Device K201379	Remark
Product Code	EOQ	EOQ	Same
Regulation No.	874.4680	874.4680	Same
Class	II	II	Same
Manufacturer	Scivita Medical Technology Co., Ltd.	Scivita Medical Technology Co., Ltd.	Same
Indication for Use	The Broncho videoscope system is designed to be used for endoscopic diagnosis and therapies within the respiratory system such as trachea, bronchi, and lungs. The Broncho videoscope System is for use in a	The Broncho videoscope system is designed to be used for endoscopic diagnosis and therapies within the respiratory system such as trachea, bronchi, and lungs. The Broncho videoscope System is for use in	Similar Analysis 1

	hospital environment. This Full HD Visualization Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the electronic endoscopes, displaying the images on its LCD display and/or external monitor within the field of view from the body cavity. This Single-use Broncho Videoscope is intended to use in conjunction with endoscopic image processor to provide images through the video monitor for observation, diagnosis, photography and treatment of the respiratory system such as trachea, bronchi, and lungs.	a hospital environment. This Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the electronic endoscopes, displaying the images on the monitor detected within the field of view from the body cavity. This Single-use Broncho Videoscope is intended to use in conjunction with endoscopic image processor (HDVS-S100A and HDVS-S100D) to provide images through the video monitor for observation, diagnosis, photography and treatment of the respiratory system such as trachea, bronchi, and lungs.	
Main Configuration	Single-use Broncho Videoscope with square plug and round plug (SBV-1A-B, SBV-1A-P, SBV-1B-B, SBV-1B-P, SBV-1C-B, SBV-1C-P)	Single-use Broncho Videoscope with square plug. (SBV-1A-B, SBV-1A-P, SBV-1B-B, SBV-1B-P, SBV-1C-B, SBV-1C-P)	Similar Analysis 2
	Full HD Visualization Endoscopic Image Processor	Endoscopic Image Processor	
Single use/ Reuse	Endoscope: Single use Image Processor: Reuse	Endoscope: Single use Image Processor: Reuse	Same
Sterile	Yes, for disposable endoscope	Yes, for disposable endoscope	Same
Anatomical Site	Respiratory system such as trachea, bronchi, and lungs	Respiratory system such as trachea, bronchi, and lungs	Same
Where used	Hospitals	Hospital	Same
Label/Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Analysis 1- Indication for Use (IFU)

The IFU of the subject device is expressed in three parts including the whole system's IFU, the Image Processor' s IFU and the Broncho Videoscope's IFU. The IFU of the predicate device is also expressed in

three parts including the whole system's IFU, the Image Processor' s IFU and the Broncho Videoscope's IFU. The IFU statements of the whole system and Broncho Videoscope of subject device are same as those of the predicate device. Compared with the predicate device, the image resolution of the subject device can reach full HD. The Full HD Visualization Endoscopic Image Processor has a LCD display. The Full HD Visualization Endoscopic Image Processor of the subject device can display the images on its LCD display and/or external monitor. The Endoscopic Image Processor of the predicate device can display the images on the external monitor. The image quality testing of the subject device demonstrate that the image quality of the integratiy LCD display is acceptable.

Based on above analysis, the indication for use of the subject device and the predicate device is only different in expression. The difference will not affect the safety and effectiveness of the subject device.

Analysis 2- Main Configuration
The Broncho Videoscope of subject device has extra round plug comparing with the predicate device. The image quality testing of the subject device The image quality testing of the proposed device include intensity uniformity test , depth of field test, resolution test, color reproduction test, geometric distortion test, image frame frequency and system delay test and noise and dynamic range test demonstrate that the image quality of the device does not affected by the different plug.

Table 2. Specifications Comparison of Endoscopic Image Processor

ITEM	Full HD Visualization Endoscopic Image Processor	Endoscopic Image Processor K201379	Remark
Model	HDVS-S300A, HDVS-S300B, HDVS-S300C, HDVS-S300D	HDVS-S100A HDVS-S100D	/
Dimension	332mm (W)×241.9mm (D) ×56.5mm (H)	300(W)×57(H)×225(D) mm	Similar Analysis 3
Weight	About 2.5Kg	About 2.5Kg	Same
Is there an integrated LCD display?	Yes	No	Different Analysis 4
Freeze	Create static picture of dynamic image	Create static picture of dynamic image	Same
Zoom	Magnification of image is 1 times, 1.5 times and 2 times (full screen), three stages cycling adjustment.	By pressing the ZOOM button, the original image (74% contrasting to vertical screen) can be enlarged to 89% and 100% of the vertical screen, respectively.	Different Analysis 5

LED Brightness Adjustment	Adjust LED brightness by three models (L, M, H). L: low Led light intensity M: moderate Led light intensity H: high Led light intensity	Three modes of Led light intensity can be chosen when pressing the LED (L M H) button in order. L: low Led light intensity M: moderate Led light intensity H: high Led light intensity	Same
RECORD (PHOTO)	Press the RECORD (PHOTO) button on the touchscreen, the images will be captured by the electronic endoscope and stored to the storage device.	Once pressed the RECORD (PHOTO) button, the photo will be taken and stored in the storage device.	Same
RECORD (VIDEO)	Press the RECORD (VIDEO) button on the touchscreen, the equipment starts to record. Press the button again to end the recording. The video recorded will automatically store to the storage device (photographing function can be performed when recording video).	After pressing the RECORD (VIDEO) button, the endoscopic image processor starts to record the video, and it will keep recording until the RECORD (VIDEO) button is pressed for the second time.	Same
Auto white balance	Automatically adjusted	Automatically adjusted	Same
Video Signal Output	SDI, HDMI video signal output port	SDI, DVI video signal output port	Different Analysis 6
Foot switch	There is no Foot switch.	The foot switch can control the functions of gain, image freezing, electronic magnification, contour emphasis and image recording.	Different Analysis 7
Power Supply	It has a rechargeable lithium-ion battery. It has two power supply modes, which are internal and external power supply. The external power supply is AC100V-240V,50/60Hz.	It has only an external power supply, 100-240V±10% AC, 50/60Hz.	Different Analysis 8

Disinfection method	75% ethanol	75% ethanol	Same
Communication with endoscope	Provided	Provided	Same

Analysis 3-Dimension

The dimension for the subject image processor is different form the predicate device. The dimension are just in physical specification and this difference will not raise any issues in safety and effectiveness.

Analysis 4-Is there an integrated LCD display?

The subject image processor has extra integrated LCD display comparing with the predicate device. However, the color reproduction performance of the integrated LCD display has been tested in the ***Tab 57 Color Reproduction Test Report***, the test results demonstrated the performance of the integrated LCD display is acceptable.

Analysis 5-ZOOM

The ZOOM function of the subject image processor is different from predicate image processor. The ZOOM function is used to adjust the image size without changing the image content; this difference will not raise any issues in safety and effectiveness.

Analysis 6-Video Signal Output

The types of video signal output are different between subject image processor and predicate image processor. The subject device has HDMI and SDI interface, the predicate device has SDI and DVI interface. The image quality of the subject device and predicative device have been tested in the quantitative image quality testing**..** The test results demonstrate that the image quality of the subject device was equivalent to that of the predicate device. Therefore, the difference on video signal output will not affect the safety and effectiveness of the subject device.

Analysis 7- Foot switch

The foot switch of the subject device is different between subject image processor and predicate device. There is no foot switch for subject device. The subject device has a LCD display. The main unit function control can be realized by clicking the LCD display. The main unit function button of the predicate device is located in the front panel, and the main unit function can be controlled by the foot switch. The LCD display of the subject device is 13.3 inches, and the area of touchscreen is large, and the function button icon is clear. Therefore, the difference will not affect the safety and effectiveness of the subject device.

Analysis 8- Power Supply

There are two power supplies for subject device, which are internal and external power supply. The external power supply for subject device is same as predicate device. So the subject device has extra internal power supply comparing with the predicate device. The internal power supply for subject device is an embedded rechargeable lithium-ion battery, the electrical safety and electromagnetic compatibility has been test in, the

test results demonstrated the internal power supply is safety.

Table 3. Specifications Comparison of Broncho Videoscope

ITEM	Subject Device	Predicate Device K210379	Remark
Model	SBV-1A-B, SBV-1A-P SBV-1B-B, SBV-1B-P SBV-1C-B, SBV-1C-P	SBV-1A-B, SBV-1A-P SBV-1B-B, SBV-1B-P SBV-1C-B, SBV-1C-P	Same
Maximum Outer Diameter of Insertion Section	3.2mm (SBV-1A-B; SBV-1A-P); 4.9mm (SBV-1B-B; SBV-1B-P); 6.2mm (SBV-1C-B; SBV-1C-P);	3.2mm (SBV-1A-B; SBV-1A-P); 4.9mm (SBV-1B-B; SBV-1B-P); 6.2mm (SBV-1C-B; SBV-1C-P);	Same
Minimum Instrument Channel Width	1.15mm (SBV-1A-B; SBV-1A-P); 1.95mm (SBV-1B-B; SBV-1B-P); 2.75mm (SBV-1C-B; SBV-1C-P);	1.15mm (SBV-1A-B; SBV-1A-P); 1.95mm (SBV-1B-B; SBV-1B-P); 2.75mm (SBV-1C-B; SBV-1C-P);	Same
Working Channel	Φ1.2mm (SBV-1A-B; SBV-1A-P); Φ2.0mm(SBV-1B-B; SBV-1B-P); Φ2.8mm (SBV-1C-B; SBV-1C-P);	Φ1.2mm(SBV-1A-B; SBV-1A-P); Φ2.0mm(SBV-1B-B; SBV-1B-P); Φ2.8mm(SBV-1C-B; SBV-1C-P);	Same
Working Length	600mm	600mm	Same
Total Length	920mm	920mm	Same
Bending angle	Up:220°,Down:220°	Up:220°,Down:220°	Same
Field of View	120°	120°	Same
Direction of View	0°	0°	Same
Depth of Field	0.5～120mm	0.5～120mm	Same
Endoscope Illumination	LED light is placed at the distal end of the endoscope	LED light is placed at the distal end of the endoscope	Same
Method of Sterilization	EO	EO	Same
Plug type	Square plug Round plug	Square plug	Similar Analysis 2

Table 4. Safety Comparison

ITEM		Subject Device	Predicate Device K210379	Remark
Electrical Safety		Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC		Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Particular requirements		Comply with IEC 60601-2-18	Comply with IEC 60601-2-18	Same
Bending section		Pebax	Pebax	Same
Insertion section		Nylon PA12/PEEK	Nylon PA12/PEEK	Same
Connecting section		PET	PET	Same
Distal end section	CMOS front end	Glass	Glass	Same
	Injection head	Sulfone polymer	Sulfone polymer	Same
	Distal end connecting ring	304 SUS	304 SUS	Same
	Working Channel	Pebax	Pebax	Same
Drainage tube		PC	PC	Same
Irrigation valve		PC; silicone rubber	PC; silicone rubber	Same
Suction device	Suction nozzle	PC	PC	Same
	Suction button	Silicone rubber	Silicone rubber	Same
	Suction access	Pebax	Pebax	Same
Biocompatibility		No Cytotoxicity	No Cytotoxicity	Same
		No Sensitization	No Sensitization	
		No Irritation	No Irritation	
Sterilization (Single-use Broncho Videoscope)				
Method		EO sterilization	EO sterilization	Same
SAL		10-6	10-6	Same

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, Broncho Videoscope System is as safe, as effective, and performs as well and is substantially equivalent to the legally marketed predicate device cleared under K210379.