July 28, 2021

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

Re: K210379
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: June 21, 2021
Received: June 28, 2021

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 (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,

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1C: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201379

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 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.

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

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

The assigned 510(k) Number: K210379

1. Date of Preparation: 06/21/2021

2. Sponsor Identification

Scivita Medical Technology Co., Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Broncho Videoscope System
Common Name: Bronchoscope Systen

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 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.

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

Table 1 Product Model

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
	Endoscopic Image Procesosr	HDVS-S100A, HDVS-S100D

The Single-use Broncho Videoscope is a single use device. The Single-use Broncho Videoscope has six models 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). The single-use Broncho Videoscope is a single-channel endoscope. 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 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 Endoscopic Image Processor is a reusable device. The Endoscopic Image Processor has two models. The only difference between the two models is that the HDVS-S100A has Enhance function and the HDVS-S100D does not have the Enhance function.

5. Identification of Predicate Device

510(k) Number: K191828
Product Name: Vathin Video Bronchoscope System

6. Non-Clinical Test Conclusion

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:

- ISO 10993-7:2008 Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals
- ASTM F88/F88M-15 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
- ISO 8600-1:2015 Endoscopes-Medical endoscopes and endotherapy devices-part 1: General requirements
- ISO 8600-3:1997/Amd1:2003 Optics and optical instruments-Medical endoscopes and endoscopic accessories-Part 3: Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-4:2014 Endoscopes-Medical endoscopes and endotherapy devices-Part 4: Determination of maximum width of insertion portion
- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance, including the US National Differences

- IEC 60601-1-2:2014 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- 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
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 62471:2006 Photobiological Safety of Lamps and Lamp Systems.
- ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices

Biocompatibility testing

The contact level of the proposed device is mucosal membrance, and the contact duration is limited contact (<24 hours). The proposed endoscope was evaluated for the following tests. The results ofthe biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device.

- Cytotoxicity,
- Sensitization,
- Intracutaneous,

Software verification and validation testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Bench performance testing

Optical performance testing

- Photobiological safety test according to IEC 62471: 2006;
- Color reproduction, Resolution, Depth of view, Geometric distortion, Image intensity uniformity), Image frame frequency and system delay testing compared with the predicate device.

Physical/functional performance testing

- Suction system function test was performed compared with the predicate device, and irrigation valve leakage test was performed on the proposed device;

Endoscope and image processor use-life testing

The optical performance comparison test was conducted on the un-aged Single-use Broncho Videoscope and aged Single-use Broncho Videoscope. The test results demonstrate that the optical performance of the aged endoscope is similar as those of the un-aged endoscope.

A use-life verification was conducted to determine the image system's use life. After accelerating aging and running, the qualitative was conducted on the image processor. The test results demonstrate that the performance of the proposed system doesn't reduced after accelerating aging and running, and the use-life statement of six years are accepted. In addition, the quantitative optical performance comparison testing was conducted on the new image processor and the image processor after accelerating aged and running. The test results demonstrate that the optical performance of the image process after accelerating aged and running is similar as those of the new one.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 SE Comparison

ITEM	Proposed Device	Predicate Device K191828	Remark
Product Code	EOQ	EOQ	Same
Regulation No.	874.4680	874.4680	Same
Class	II	II	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 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.	The Vathin® H-SteriScope™ I Single-use flexible Video Bronchoscope have been designed to be used with the Vathin® VisionCenter™ 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.	Different
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	Airways and tracheobronchial tree	Different
Where used	Hospitals	Hospital	Same
Main Configuration	Single-use Broncho Videoscope	Vathin® H-SteriScope™ I Single-use flexible Video Bronchoscope	Same
	Endoscopic Image Processor	Vathin® VisionCenter™ I Digital Video Processor	
Label/Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Scope type	Flexible	Flexible	Same
Field of view	120°	110°	Different
Direction of view	0°	0°	Same
Depth of field	0.5~120mm	3~30mm	Different
Sensor type	CMOS	CMOS	Same
Max. 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);	2.2 mm, 3.2mm, 4.1mm, 4.7mm, 4.9mm, 5.2mm, 5.8mm, 6.0mm, 6.2mm	Different
Up/down deflection	Up: 220° Down: 220°	Up:210° Down: 210°	Different
Work length	600mm	600mm, 700mm	Different
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);	0mm, 1.2mm, 1.7mm, 2.0mm, 2.2mm, 2.4mm, 2.8mm, 3.0mm, 3.2mm	Different
Illumination source	LED	LED	Same
Power supply	AC: 100-240V±10% 50/60 Hz	AC 100-240V 50-60Hz	Same
Dimension	300(W)×57(H)×225(D) mm	235(W) ×210(H) ×70(D)mm	Different
Weight	About 2.5Kg	Unknown	
Input power	100VA	Unknown	Different
Video signal output	DVI:1 SDI: 2	DVI	Different
Auto white balance	Automatically adjusted	Manually adjusted	Different
Communication with endoscope	Provided	Provided	Same
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
Product Performance	Comply with ISO 8600	Comply with ISO 8600	Same
Patient-contact component and material			
Bending section	Pebax	Unknown	Different

Insertion section	Nylon PA12/PEEK			
Connecting section	PET			
Distal end section	CMOS front end	Glass		
	Injection head	Sulfone polymer		
	Distal end connecting ring	304 SUS		
	Working Channel	Pebax		
Drainage tube	PC			
Irrigation valve	PC; silicone rubber			
Suction device	Suction nozzle	PC		
	Suction button	Silicone rubber		
	Suction access	Pebax		
Sterilization (Single-use Broncho Videoscope)				
Method	EO sterilization		EO sterilization	Same
SAL	10^{-6}		10^{-6}	Same

Different- Indication for Use

Firstly, the indication for use of the proposed device is different from that of the predicate device in expression. The indications for use of the proposed device is provided in the form of system's indications for use, image processor's indications for use and disposable endoscope's indications for use. The predicate device doesn't provide the whole system's indications for use. Many cleared endoscope system adopted this expression form of indications for use. Therefore, the difference on expression form of indications for use will not raise new questions on safety and effectiveness of the propose device.

Second, the endo-therapy accessories and ancillary equipment are included in the predicate device's indications for use statement. While the proposed device does not include these in the indications for use statement. The proposed device also can be used with the accessories and ancillary equipment during clinical, and the information of accessories and ancillary equipment is listed in the section 3.5 of User Manual of Single-use Broncho Videoscope. Therefore, this difference will not raise new questions on safety and effectiveness of the propose device.

Thirdly, the intended clinical anatomic sites of the predicate device including airways and tracheobronchial tree; the intended clinical anatomic site of the proposed device including trachea, bronchi, and lungs. However, the trachea, bronchi, and lungs are collectively called the respiratory system or the airways and tracheobronchial tree. Therefore, the proposed device and predicate device are applicable to the same clinical anatomic sites. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.

Finally, the intended working place is included in the predicate device's indications for use, which is hospital environment. Although, the intended working place of the proposed device isn't included in its indications for use, the proposed device also will be used in the hospital environment. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.

Both devices are used for endoscopic diagnosis and therapies within the respiratory system. Based on above analysis, the indication for use of the proposed device and the predicate device is only different in expression. The difference will not affect the safety and effectiveness of the proposed device.

Different- Anatomical Site

The anatomical site of the proposed device is different from the predicate device. However, the difference is only in expression. The trachea, bronchi, and lungs are collectively called the respiratory system or the airways and tracheobronchial tree as expressed in Analysis 1-Indication for Use. Therefore, the proposed device and predicate device are applicable to the same clinical anatomic sites. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.

Different- Field of view

The proposed device has a wider range of field of view than the predicate device to give physicians more options for diagnosis and treatment based on the patient's condition. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.

Different- Depth of field

The proposed device has a wider range of depth of field than the predicate device to give physicians more options for diagnosis and treatment based on the patient's condition. Therefore, this difference will not raise new question on safety and effectiveness of the proposed device.

Different- Max. outer diameter of insertion section

The Max. outer diameter of insertion section of the proposed device is different from the predicate device. However, the Max. outer diameter of insertion section of the proposed device is available in only three specifications, 3.2mm, 4.9mm and 6.2mm. The Max. outer diameter of insertion section of the predicate device has more specifications than the proposed device, but it also includes 3.2mm, 4.9mm and 6.2mm. Therefore, the difference will not affect the safety and effectiveness of the proposed device

Different- Up/down deflection

The up/down deflection of the proposed device is different with the predicate device. However, the

up/down deflection of the proposed device is similar to those of the predicate device. All of the specification of the proposed device has been included in the user manual, including bend angle. The surgeon will select the proper endoscope based on her/his experiences and clinical conditions.

This slight difference on up/down deflection between the proposed device and predicate devices does not affect the safety and effectiveness of the proposed device

Different- Work length

The work length of the proposed device is different from the predicate device. However, the working length of the proposed device is available in 600mm. The working length of the predicate device has more specifications than the proposed device, but it also includes 600mm. In addition, all of the specification of the proposed device has been included in the user manual, including working length. The surgeon will select the proper endoscope based on her/his experience and clinical conditions. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different- Min. inner diameter instrument channel

The Min. inner diameter instrument channel of the proposed device is different from the predicate device. However, the range of the Min. inner diameter instrument channel of the proposed device is within the range of the Min. inner diameter instrument channel of the predicate device. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different-Dimension and weight

The dimension for the proposed image processor is different from predicate image processor and the weight of the predicate device is unknown. However, the dimension and weight is just in physical specification and this difference will not raise any issues in safety and effectiveness.

Different- Input power

The input power for the predicate image processor is unknown. However, the input power of proposed image processor complies with IEC 60601-1 standard, the difference in input power is just the difference in device design. Therefore, this difference on input power is considered not affect the safety and effectiveness of the proposed device.

Different-Video Signal Output

The types of video signal output are different between proposed image processor and predicate image processor. The proposed device has DVI and SDI interface, the predicate device has DVI interface. The image quality of the proposed device and predicative device have been tested in the quantitative image quality testing. The test results demonstrate that the image quality of the proposed 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 proposed device.

Different- Auto white balance

The type of auto white balance of the proposed device is different between proposed image processor and predicate device. Automatic white balance is more convenient and does not require the user to adjust manually. The proposed device is automatically adjusted and the predicate device is manually adjusted. However, the color reproduction test has been tested on the proposed device and predicate device and the test results demonstrate that the image quality of the proposed device was better to the predicate device. In addition, there are a lot of image processors already on the market use automatic white balance. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different- Patient-contact component and material

The patient-contact material of the predicate device is unknown. However, the biocompatibility tests were conducted on the material consisted of the proposed device and the test result shows that the material does not raise the adverse effect on the material. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.