March 19, 2024

Scivita Medical Technology Co., Ltd.
Jiang Dan
Senior Regulatory Affairs Specialist
No.2, Qingqiu Street, Suzhou Industrial Park
Suzhou, Jiangsu 215000
China

Re: K250210
Trade/Device Name: 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); Endoscopic Image Processor (HDVS-S100A, HDVS-S100D))
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: February 20, 2025
Received: February 20, 2025

Dear Jiang Dan:

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.

510(k) Number *(if known)*
K250210

Device Name
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); Endoscopic Image Processor (HDVS-S100A, HDVS-S100D))

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.

The 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.

The 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.

The 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.

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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510(k) #: K250210

510(k) Summary

Prepared on: 2025-03-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Scivita Medical Technology Co.,Ltd.
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Correspondent Contact Telephone	86-512-81877788
Correspondent Contact	Ms. Jiang Dan
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	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, Endoscopic Image Processor: HDVS-S100A, HDVS-S100D)
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope (Flexible Or Rigid)
Regulation Number	874.4680
Product Code(s)	EOQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231521	Broncho Videoscope System	EOQ
K210379	Broncho Videoscope System	EOQ

Device Description Summary

21 CFR 807.92(a)(4)

The subject device, Broncho Videoscope System, is consisting of a Single-use Broncho Videoscope and a Full HD Visualization Endoscopic Image Processor or 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.

The Single-use Broncho Videoscope 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 models, which are available in three kinds of outer diameter of insertion section (Φ2.8mm, Φ4.2mm and Φ5.6mm), one working length (600mm), two different material of the insertion section (Nylon and PEEK) and two plug types (Square type and round type). The six models with round type have been cleared in K210739.

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, they have the same hardware and the difference is only on the image adjustment functions.

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.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

The 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.

The 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.

The 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the subject device is the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technical characteristics as the predicate device. They have the same specifications, designed structure and materials. This submission is intended to provide new biocompatibility data for FDA review to ensure the safety and effectiveness of Broncho Videoscope System.

Specifically, the North American Science Associates (NAMSA) retested the biocompatibility tests (cytotoxicity, sensitization, irritation) of models with tail letter "-B", SBV-1A-B, SBV- 1B-B, SBV-1C-B, and its scope of ASCA accreditation includes all three aforementioned test methods. The biocompatibility tests (cytotoxicity, sensitization, irritation) of the models with tail letter "-P", SBV-1A-P, SBV-1B-P, SBV-1C-P, were retested in WuXi Apptec Suzhou, where only the cytotoxicity)/ test method is within the scope of ASCA accreditation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The biocompatibility tests were re-conducted on the representative models per the requirements of ISO 10993-1, including cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-23) tests. The test results demonstrated that the subject device complies with the requirements of the standards.

The non-clinical tests provided in this submission demonstrate that the subject Broncho Videoscope System is substantially equivalent to the predicate device.