October 23, 2024

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

Re: K240289
Trade/Device Name: Full HD Endoscopic Image Processor (HDVS-S200A, HDVS-S200B, HDVS-S200C, HDVS-S200D)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: September 24, 2024
Received: September 24, 2024

Dear Dan Jiang:

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)*

K240289

Device Name

Full HD Endoscopic Image Processor (HDVS-S200A, HDVS-S200B, HDVS-S200C, HDVS-S200D)

Indications for Use *(Describe)*

This product is used in combination with Single-use Broncho Videoscope (SBV-1A-B, SBV-1A-P, SBV-1B-B, SBV-1B-P, SBV-1C-B, SBV-1C-P) to process the image collected by the electronic endoscope and transfer them to the monitor for imaging.

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) #: K240289

510(k) Summary

Prepared on: 2024-10-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Scivita Medical Technology Co.,Ltd.
Applicant Address	No.2, Qingqiu Street, Suzhou Industrial Park, 215000 Suzhou, Jiangsu Prov., P.R.CHINA Suzhou 215000 China
Applicant Contact Telephone	86-512-81877788
Applicant Contact	Mrs. Wu Ruqin
Applicant Contact Email	wuruqin@scivitamedical.com
Correspondent Name	Scivita Medical Technology Co.,Ltd.
Correspondent Address	No.2, Qingqiu Street, Suzhou Industrial Park, 215000 Suzhou, Jiangsu Prov., P.R.CHINA Suzhou 215000 China
Correspondent Contact Telephone	86-512-81877788
Correspondent Contact	Ms. Jiang Dan
Correspondent Contact Email	ra@scivitamedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Full HD Endoscopic Image Processor (HDVS-S200A, HDVS-S200B, HDVS-S200C, HDVS-S200D)
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope (Flexible Or Rigid)
Regulation Number	874.4680
Product Code	EOQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210379	Endoscopic Image Processor	EOQ

Device Description Summary

21 CFR 807.92(a)(4)

Full HD Endoscopic Image Processor is used in combination with Single-use Broncho Videoscope (SBV-1A-B, SBV-1A-P, SBV-1B-B, SBV-1B-P, SBV-1C-B, SBV-1C-P) to process the image collected by the electronic endoscope and transfer them to the monitor for imaging.

This product is composed of Full HD Endoscopic Image Processor host, foot switch, power cable and video cable. Video cable includes SDI video cable and DVI video cable. The foot switch is optional.

There are four models (HDVS-S200A, HDVS-S200B, HDVS-S200C, HDVS-S200D) for Full HD Endoscopic Image Processor, and the

difference between the four models is only the difference in structure configuration.

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

This product is used in combination with Single-use Broncho Videoscope (SBV-1A-B, SBV-1A-P, SBV-1B-B, SBV-1B-P, SBV-1C-B, SBV-1C-P) to process the image collected by the electronic endoscope and transfer them to the monitor for imaging.

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

Indications for Use of the subject device is basically the same as the predicate device. Both the subject device and the predicate device is intended to connect with the electronic endoscopes for endoscopic diagnosis and therapies, process the image and transfer the image signal to the monitor for imaging. The indications for use of the subject device and the predicate device are only different in expression. This difference will not affect the safety and effectiveness of the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

Full HD Endoscopic Image Processor (subject device) and the Endoscopic Image Processor (predicate device, Scivita, K210379) share the same technological characteristics. Full HD Endoscopic Image Processor is an upgrade of the Endoscopic Image Processor. Compared with Endoscopic Image Processor, Full HD Endoscopic Image Processor has two kinds of electronic endoscope port, round plug and square plug, which support electronic endoscope with any of two interface types. In addition, Full HD Endoscopic Image Processor has menu selection and image adjustment functions. Users can switch the endoscope display of different pixels, display style, language type, date setting, replay of pictures or video, and adjust the imaging clarity level. These differences do not raise different question of safety and effectiveness of the subject device.

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

The following performance data were provided in support of the substantial equivalence determination. The test results demonstrated that the subject device complies with the standard requirements.

1) Electrical Safety and Electromagnetic Compatibility Summary:

The electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1:2005+A1:2012+A2:2020 (Edition 3.2), IEC 60601-2-18:2009 (Edition 3.0) and IEC 60601-1-2:2014+A1:2020 (Edition 4.1).

2) Optical performance characteristics:

Optical performance comparison testing was conducted on the subject device and predicate device. The optical performance test includes:

Resolution;
Depth of field,;
Color Reproduction;
Noise and Dynamic Range;
Intensity Uniformity;
Geometric Distortion;
Image Frame Frequency and System Delay test.

3) Service life (Use Life) of the Image Processor

A use-life verification was conducted to determine the system's use life.
After accelerating aging and running, the qualitative and quantitative optical performance were conducted on the Full HD Endoscopic Image Processor.

4) Package Validation:

Simulated distribution was conducted per ASTM D4169-22 after accelerated aging.

The clinical data is not applicable.

The nonclinical test were conducted to demonstrate that the subject is as safe and effective as the predicate.