January 20, 2026

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

Re: K251338
Trade/Device Name: Cholangioscope Visualization System (Single-use Video Cholangioscope: SCV-P-01G, SCV-P-02G; Full HD Visualization Endoscopic Image Processor: HDVS-S300A, HDVS-S300B, HDVS-S300C, HDVS-S300D)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN, FET
Dated: December 19, 2025
Received: December 19, 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,

SHANIL P. HAUGEN -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
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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)*
K251338

Device Name
Cholangioscope Visualization System (Single-use Video Cholangioscope: SCV-P-01G, SCV-P-02G;
Full HD Visualization Endoscopic Image Processor: HDVS-S300A, HDVS-S300B, HDVS-S300C, HDVS-S300D)

Indications for Use *(Describe)*
This Single-use Video Cholangioscope is intended to use in conjunction with endoscopic image processor to provide images for diagnostic and therapeutic applications in the pancreatico-biliary system and to provide a working channel for other endoscopic accessories.

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.

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) #: K251338

510(k) Summary

Prepared on: 2026-01-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Scivita Medical Technology Co.,Ltd.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cholangioscope Visualization System (Single-use Video Cholangioscope: SCV-P-01G, SCV-P-02G; Full HD Visualization Endoscopic Image Processor: HDVS-S300A, HDVS-S300B, HDVS-S300C, HDVS-S300D)
Common Name	Endoscope and accessories
Classification Name	Choledochoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FBN, FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183636	SpyScope DS II Access and Delivery Catheter	FBN

Device Description Summary

21 CFR 807.92(a)(4)

The subject device, Cholangioscope Visualization System, comprises two components: the Single-use Video Cholangioscope and the Full HD Visualization Endoscopic Image Processor.

The Single-use Video Cholangioscope is a single use sterile device. It is composed of working channel, control wheel, operation section, insertion section (integrated with a video image sensor and lighting components), plug section, connection cable, water supply channel, suction channel and accessory- irrigation valve.

The operation section allows users to connect and operate the product. It includes two control wheels (large/small control wheel) to control the bending section at the insertion section to bend in four directions, a lock mechanism can be rotated clockwise to lock the control wheel in its current position, a working channel port can be used for inserting accessory and suction, a bundle mechanism is used to fix the Single-use Video Cholangioscope to the duodenoscope, a water supply port for connecting to the water supply tube, a suction port for connecting to suction tube with a flow control value, and a plug section for connecting with the image processor.

The insertion section can be inserted in patient entirely, and it includes a bending section and a distal end. The bending section can be bent ≥50° in four directions by the control wheel. The distal end includes a miniature Complementary Metal Oxide Semiconductor (CMOS) camera, two light-emitting diode (LED) illumination module, two water supply channels for inserting accessories and one working channel for discharging liquid to the suction tube.

The accessory-irrigation value can be connected to the working channel port to expand the working channel, and provide an injection-suction dual-purpose port that can be used for liquid supply or suction through the working channel.

This Full HD Visualization Endoscopic Image Processor is used for endoscopic diagnosis and therapies. It connects to the electronic endoscopes, displaying the images within the field of view from the body cavity on its LCD display and/or external monitor. The Full HD Visualization Endoscopic Image Processor has four models, they have the same hardware and the difference is mainly in the image adjustment functions.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This Single-use Video Cholangioscope is intended to use in conjunction with endoscopic image processor to provide images for diagnostic and therapeutic applications in the pancreatico-biliary system and to provide a working channel for other endoscopic accessories.

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device and predicate device are similar. They are both intended to use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system.
The indications for use of the subject device and the predicate device is only different in expression. This difference does not raise different questions of safety and effectiveness of the subject device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject Single-use Video Cholangioscope and the predicate SpyScope DS II Access and Delivery Catheter (K183636) share the similar technological characteristics, including CMOS image sensors for visualization, two LED illumination light modules for lighting, one working channel for inserting accessory and suction, two irrigation channels for water supply and four directions bending function controlled by the wheel on the handle.

The technological characteristics difference between the subject and predicate endoscope is that the lighting method (internal LED for subject device, and external LED for predicate device), dimensions (e.g. outer diameter of insertion section, working channel, working length) and optical specifications (depth of field, bending angle) are slightly difference. However, these differences do not raise different question of safety and effectiveness of the subject device.

The main configuration, dimension and weight,video signal output, white balance, image processor function and LCD display of the subject Full HD Visualization Endoscopic Image Processor are different from or similar as the predicate SpyGlass DS Digital Controller (K183636). These differences will not raise new question on safety and effectiveness of the subject device based on the comparison test report of the subject device and predicate 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.

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).

Photobiological safety:
The photobiological safety testing was tested in accordance with IEC 62471:2006.

Optical performance:
The subject device was designed to comply with applicable parts of ISO 8600-1: 2015, ISO 8600-3:2019, ISO 8600-4: 2014. Optical performance comparison testing was conducted on the subject device and predicate device. The optical performance test includes Intensity Uniformity, Depth of field, Resolution, Color Reproduction, Geometric Distortion, Noise and Dynamic Range, Image Frame Frequency and System Delay test.

Machanical Performance Testing:
The machanical performance testing was conducted to demonstrate the subject cholangioscope can function as intended. The machanical perfermance testing includs the leakage testing, tensile strength testing and bending angle testing.

Shelf Life and Service Life (Use Life):
Three years shelf life was validated by accelerated aging per ASTM F1980-21 for Single-use Video Cholangioscope, and ten years use-life verification was conducted for Full HD Visualization Endoscopic Image Processor.

Package Validation:
Simulated distribution was conducted per ASTM D4169-22 after accelerated aging.
Package integrity testing of the Single-use Video Cholangioscope was conducted before the accelerated aging and after the simulated distribution according to ASTM F1886/F1886M-16, ASTM F88/F88M-21, ASTM F1929-15.

ERCP Model Simulation Testing
An in vitro ERCP model simulation test was conducted to demonstrate the subjet cholangioscope may perform as intended when used with the duodenoscope during Endoscopic Retrograde Cholangiopancreatography Procedures (ERCP).

The clinical data is not applicable.

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