August 27, 2025

Shanghai AnQing Medical Instrument Co., Ltd.
Shuwen Fan
RA Manager
3 & 4 Floor, No.2 Building, 366 Huiqing Rd
East Zhangjiang High-Tech Park
Shanghai, 201201
China

Re: K251752
Trade/Device Name: Flexible Bronchoscope (BS27U-12EU, BS27U-12US, BS38U-20EU, BS38U-20US)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 9, 2025
Received: June 9, 2025

Dear Shuwen Fan:

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)*

K251752

Device Name

Flexible Bronchoscope (BS27U-12EU, BS27U-12US, BS38U-20EU, BS38U-20US)

Indications for Use *(Describe)*

The Flexible Bronchoscopes have been designed to be used with the video processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.
The Flexible Bronchoscope is for use in a hospital environment. The Flexible Bronchoscope is a single-use device designed for use in adults.

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) #:

510(k) Summary

Prepared on: 2025-08-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shanghai AnQing Medical Instrument Co., Ltd.
Applicant Address	3 & 4 Floor, No.2 Building, 366 Huiqing Rd, East Zhangjiang High-Tech Park Shanghai 201201 China
Applicant Contact Telephone	+86-21-61117375
Applicant Contact	Ms. Shuwen Fan
Applicant Contact Email	ra_dept@anqing-sh.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Flexible Bronchoscope (BS27U-12EU, BS27U-12US, BS38U-20EU, BS38U-20US)
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
K243497	Flexible Bronchoscope	EOQ

Device Description Summary

21 CFR 807.92(a)(4)

The Flexible Bronchoscope (Model: BS27U-12EU, BS27U-12US, BS38U-20EU, BS38U-20US) is intended to be used with the Portable Video Processor (cleared via K243497). The Flexible Bronchoscope is inserted through the airways and tracheobronchial tree during bronchoscopy, and when used with the compatible video processor and monitor, the endoscope system can be operated as intended and indicated. The Flexible Bronchoscope is a single-use endoscope, which consists of a Handle, an Insertion Section, and an Endoscope Connector. The handle includes a deflection lever, a lever lock, a push button for picture taking/video recording, a push button for suction, a connector for suction tubing, a Luer port for insertion of accessory devices and irrigation to the working channel and a LED for illumination. The insertion section contains one working channel, wiring to transmit the image signals to the video processor, and two optical fibers to transmit illumination from the handle to the distal tip. The distal bending section of the insertion section is controlled by the user via the deflection lever on the handle. The distal end of the insertion section contains a CMOS sensor for capturing image and transmitting it to the video processor, optical fibers for transmitting illumination from the LED inside the handle, and the distal opening of the working channel. The Endoscope Connector connects the endoscope handle to the video processor, which provides power and processes video signals from the endoscope. Same as the predicate, the subject device is also provided in 2 deflection versions (US/EU deflection).

Mechanism of action:
The light emitted from the distal tip of the Flexible Bronchoscope is irradiated into the body cavity, and the light reflected from the

cavity enters the optical system and is captured by the CMOS image sensor. The CMOS acquisition image is controlled by the CMOS drive circuit, and the RGB video signal is output to the video processor. The video processor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the build in monitor or attached monitor. The video processor also controls the brightness of the LED on the endoscope.

Flexible Bronchoscope has the following physical and performance characteristics:
- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera at the distal tip
- LED in the handle and transmitted to the distal tip by optical fibers
- Sterilized by Ethylene Oxide
- For single use

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

The Flexible Bronchoscopes have been designed to be used with the video processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.
The Flexible Bronchoscope is for use in a hospital environment. The Flexible Bronchoscope is a single-use device designed for use in adults.

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

The indication for use of the subject device and the predicate device(s) are the same.

Technological Comparison 21 CFR 807.92(a)(6)

1. The subject and predicate devices have the same fundamental technology, deflection, field of view, direction of view, type of imager, number of uses and sterilization method.
The subject device differs from the predicate in distal end outer diameter and patient-contacting materials. These differences do not raise different questions of safety and effectiveness as compared to the predicate, and can be evaluated through performance testing.

2. Both the subject device and predicate device provides LED illumination to the procedural site, which in the case of the predicate device is provided by the LEDs in the distal tip, whereas in the case of the subject device, the illumination is generated by the LED inside of the handle and transmitted to the distal tip via optical fibers. Optical performance testing was conducted to evaluate any impact from this design difference, and the results demonstrated that subject device is as safe and effective as the predicate.

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

1. Electrical Safety and Electromagnetic Compatibility Summary
The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:
• ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
• ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
• IEC 60601-2-18 Edition 3.0 2009-08
• IEC/TS 60601-4-2 Edition 1.0 2024-03

2.Photobiological safety
The proposed device was tested according to the following FDA recognized standards:
• IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems

3. Mechanical and Optical Performance
The proposed device was designed to comply with applicable parts of ISO 8600. Optical measurements were performed according to applicable part of ISO 8600 standard.
Mechanical characteristics were tested and include leakage tightness, bending, deflection endurance, and tensile strength testing.
In addition, based on the similarities in pixel specification of the subject device and reference device(K173727), comparative testing related to image quality parameters including direction of view, field of view, MTF/DOF, color performance, SNR/Dynamic Range, Distortion,and Image intensity uniformity was performed to support substantial equivalence. In addition, Flexible Ureterorenoscope cleared via K243857 is used as a reference device for the optical performance testing due to its identical optical design, elements in the illumination and image acquisition paths, and image sensor components.

4. The biocompatibility evaluation for the patient contacting components of the proposed device was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted: Cytotoxicity, Sensitization, Irritation, Material-mediated pyrogenicity, Acute systemic toxicity.

5. Sterilization and shelf life testing
The sterilization method has been validated to ISO 11135:2014, which has thereby determined the routine control and monitoring parameters.
EO/ECH residual test was performed according to ISO 10993-7:2008.
The shelf life of the proposed device is determined based on stability study which includes aging test according to ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier.

6. Package Validation
Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F88/F88M-21, ASTM F1929-15.
Transport and shipping testing as per ASTM D4169-22.

Clinical Tests Not Applicable.

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Flexible Bronchoscope is as safe, as effective, and performs as well as the legally marketed device identified above.