



September 15, 2025

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

Re: K252598
Trade/Device Name: Flexible Cystoscope (CY50H-20EU, CY50H-20US, CY55H-24EU, CY55H-24US)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: August 18, 2025
Received: August 18, 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,

MARK J. ANTONINO -S

Mark J. Antonino, M.S.

Assistant Director

DHT3B: Division of Reproductive,
Gynecology and Urology Devices

OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K252598

Device Name

Flexible Cystoscope (CY50H-20EU, CY50H-20US, CY55H-24EU, CY55H-24US)

Indications for Use (Describe)

AnQing Medical Single Use Flexible Cystoscope is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of the lower urinary tract, including the bladder and urethra.

The Flexible Cystoscope is intended for use in a hospital environment or medical office environment.

The Flexible Cystoscope is 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.

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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 Cystoscope (CY50H-20EU, CY50H-20US, CY55H-24EU, CY55H-24US)
Regulation Name	Endoscope and accessories
Classification Name	Cystoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FAJ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222162	Flexible Cystoscope	FAJ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Flexible Cystoscope (Model: CY50H-20EU, CY50H-20US, CY55H-24EU, CY55H-24US) is a sterile single-use endoscope which is used with the video processor cleared via K243497 for providing endoscopic imaging of the lower urinary tract, including the bladder and urethra for the purpose of diagnosis and treatment.

The CY50H-20 and CY55H-24 difference is the size of Distal End Outer Diameter and Working Channel Inner Diameter. The US and EU model are identical except the deflection versions, which is opposite from each other (EU version or US version).

The Flexible Cystoscope is a single-use endoscope, which consists of Handle, Insertion Section, Distal Tip, and Endoscope Connector. The handle includes a deflection lever, a lever lock, a push button for picture taking/video recording and a Luer port for insertion of accessory devices and irrigation to the working channel. The insertion section contains one working channel and wiring to transmit the image signals to the video processor. 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, LEDs for illumination, 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.

Mechanism of action:

The light emitted by the LED cold light source at the distal tip of the disposable Flexible Cystoscope 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 built-in screen or attached external monitor. The video processor also controls the brightness of the LEDs on the endoscope.

Flexible Cystoscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Sterilized by Ethylene Oxide
- For single use

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

AnQing Medical Single Use Flexible Cystoscope is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of the lower urinary tract, including the bladder and urethra.

The Flexible Cystoscope is intended for use in a hospital environment or medical office environment.

The Flexible Cystoscope is 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\(a\)\(6\)](#)

The subject cystoscope has similar technological characteristics as its predicate device. The only difference is that the subject device is compatible with an additional video processor cleared via K243497. The additional compatibility does not affect the safety or effectiveness of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Testing has been performed to address the risks associated with the additional compatibility and to support substantial equivalence to the predicate device(s):

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. Optical performance:

Image quality parameters including direction of view, field of view, MTF/DOF, color performance, SNR/Dynamic Range, Distortion, and Image intensity uniformity was evaluated to support substantial equivalence.

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