February 26, 2026

Shanghai AnQing Medical Instrument Co., Ltd.
Shuwen Fan
RA Manager
3 & 4 Floor, #2 Bldg., 366 Huiqing Rd.
East Zhangjiang High-Tech Park
Shanghai, 201201
CHINA

Re: K254251
Trade/Device Name: InnovexView (GC146-17, GC150-20, GC155-23)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, FAJ
Dated: December 29, 2025
Received: December 29, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

JASON ROBERTS -S

Jason R. Roberts, Ph.D.
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

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)*
K254251

Device Name
InnovexView (GC146-17, GC150-20, GC155-23)

Indications for Use *(Describe)*
The InnovexView is intended to be used for direct viewing of the cervical canal and the uterine cavity, or female urinary tract, including the bladder for the purpose of performing diagnostic and therapeutic surgical procedures.
The types of procedures where the InnovexView could offer visualization include:
• Assessment of abnormal bleeding, pelvic pain, amenorrhea and abnormal findings from hysterosalpingogram;
• Assessment of infertility and pregnancy wastage;
• Confirmation of the presence of intrauterine foreign body;
• Assist in locating submucosal fibroids and polyps targeted for removal;
• Provide visual guidance during directed biopsy, polypectomy, submucosal myomectomy, transection of intrauterine adhesions and septa.
The InnovexView can also be used to permit viewing of the female adult urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Prepared: 2026-02-25

510(k) submitter

Company Name: Shanghai AnQing Medical Instrument Co., Ltd.
Company Address: 3 & 4 Floor, No.2 Building, 366 Huiqing Rd,
East Zhangjiang High-Tech Park, 201201, Shanghai, China

Contact

Name: Shuwen Fan
Telephone: +86-21-61117375
Email: ra_dept@anqing-sh.com

Device Identification

Device trade name:	InnovexView (GC146-17, GC150-20, GC155-23)
Common Name:	Hysteroscope and accessories
Classification Name:	Hysteroscope (And Accessories)
Regulatory Class:	Class II
Regulation Number:	21 CFR 884.1690
Product Code(s):	HIH, FAJ

Legally Marketed Predicate Device

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200038	Endosee System	HIH

The predicate device has not been subject to a design-related recall.

Device Description Summary

InnovexView (Model: GC146-17, GC150-20, GC155-23) is intended to be used with the video processor (model: EA101 cleared via K243497). When used with the compatible video processor and monitor, the endoscope system can be operated as intended and indicated. InnovexView is a single-use endoscope, which consists of a Handle, an Insertion Section, and an Endoscope Cable. The handle includes a deflection lever, an inflow port and an outflow port, to which luer connectors with flow control valve can be connected, a working channel port to which, a biopsy valve can be connected. The insertion section contains a working channel for access of endoscopic accessories and distention media

outflow, space for inflow, and wiring to transmit the image signals to the video processor. The bending section at the distal portion of the insertion section is controlled by the user via the deflection lever on the handle. The distal tip of the insertion section contains a CMOS image sensor for capturing the anatomical image and transmitting video signals to the video processor, LEDs for illumination, and the distal openings of working channel and inflow. The endoscope cable connects the endoscope handle to the video processor for transmitting video signals and providing power to the LEDs.

Mechanism of action:
The light emitted from the distal tip of the InnovexView 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.

InnovexView has the following physical and performance characteristics:
- Maneuverable tip controlled by the user
- Rigid insertion cord
- LED and CMOS image sensor at the distal tip
- Sterilized by Ethylene Oxide
- For single use

Intended Use/Indications for Use

The InnovexView is intended to be used for direct viewing of the cervical canal and the uterine cavity, or female urinary tract, including the bladder for the purpose of performing diagnostic and therapeutic surgical procedures.
The types of procedures where the InnovexView could offer visualization include:

- Assessment of abnormal bleeding, pelvic pain, amenorrhea and abnormal findings from hysterosalpingogram;
- Assessment of infertility and pregnancy wastage;
- Confirmation of the presence of intrauterine foreign body;
- Assist in locating submucosal fibroids and polyps targeted for removal;
- Provide visual guidance during directed biopsy, polypectomy, submucosal myomectomy, transection of intrauterine adhesions and septa.

The InnovexView can also be used to permit viewing of the female adult urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.

Indications for Use Comparison

The InnovexView device has the same intended use as the predicate Endosee System (K200038). Both devices are intended to visualize the uterine cavity for diagnostic and therapeutic procedures, including the removal of fibroids and polyps. The indications of the subject device are within that of the subject device. Slight difference in wording does not result in new intended use of the subject device.

Comparison of Technological Characteristics

	Subject Device, InnovexView (K254251)	Predicate Device, Endosee System (K200038)
	Physical Characteristics	
Outer diameter	4.6mm(13.8Fr) to 5.5mm(16.5Fr) depending on model	4.5mm
Working Length	240mm	276mm
Working Channel	Yes	Yes
Deflection range	35°left/35°right	N/A
	Optical Characteristics	
Type of Imager	CMOS	CMOS
Field of View	110°	100°
Direction of View	Forward viewing	20°
Depth of Field	5mm~100mm	5mm~90mm
Light Source	LED at distal tip	LED at tip of cannula
	Patient Contacting Materials	
General material type of main patient-contact part	Compliance with ISO10993-1	Cannula Compliance with ISO10993-1
Duration and type of contact	"Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	Cannula "Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"
	Sterilization Methods	
Number of Users	Single-Use	Single-Use Cannula
Sterilization	EO Sterilized, SAL 10^{-6}	EO Sterilized Cannula, SAL 10^{-6}
	Technological Characteristics	
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Energy source	Electricity	Electricity

	Subject Device, InnovexView (K254251)	Predicate Device, Endosee System (K200038)
Video Processor	External video processor previously cleared, not included in current 510k.	Handheld, battery-operated a reusable, detachable Display Module as an integral part of the Endosee System.
Note: The subject and predicate devices have the same fundamental technology, type of imager, number of uses and sterilization method. The subject device differs from the predicate in working length, distal end outer diameter, deflection, field of view, direction of view, depth of field and patient-contacting materials. These differences do not raise different questions of safety and effectiveness as compared to the predicate and have been evaluated through performance testing.		

Non-Clinical Performance

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.

   Nonclinical mechanical, functional, and performance testing included:

   - Appearance (visual inspection)
   - Dimensional characteristics
   - Deflection range
   - Water resistance (leakage tightness)
   - Angle control system performance
   - Stiffness

- Torque transmission
- Inflow and outflow performance
- Connection compatibility
- Instrument channel compatibility
- Tensile strength (insertion tube–handle joint)
- Connection force (endoscope connector–video processor)
- Connection force (handle–cable interface)
- Bending fatigue
- Coaxiality
- Optical performance (field of view, direction of view, resolution, depth of field, image quality, illumination)
- Electrical safety testing

Comparative optical performance testing, including evaluation of image quality parameters such as modulation transfer function (MTF), color performance, signal-to-noise ratio(SNR)/dynamic range, distortion, and image intensity uniformity, was performed to support substantial equivalence.

4. Biocompatibility

The biocompatibility evaluation for the patient-contacting components of the proposed device was performed in accordance with ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and FDA guidance. The following testing was conducted using EO-sterilized, finished devices:

- **Cytotoxicity (MEM Elution):**
  Conducted in accordance with ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity, and USP <87> Biological Reactivity Tests, In Vitro. Extraction conditions were prepared consistent with ISO 10993-12:2012, Sample preparation and reference materials. Results demonstrated slight reactivity (Grade 1), within acceptable limits.
- **Skin Sensitization (Guinea Pig Maximization Test):**
  Performed in accordance with ISO 10993-10:2021, Tests for irritation and skin sensitization. Polar and non-polar extracts were evaluated under exaggerated conditions. No evidence of sensitization was observed.
- **Intracutaneous Reactivity (Irritation):**
  Conducted in accordance with ISO 10993-23:2021, with extraction conditions prepared per ISO 10993-12:2021. Mean irritation scores were below the threshold for classification as an irritant.
- **Acute Systemic Toxicity:**
  Performed in accordance with ISO 10993-11:2017, Tests for systemic toxicity. No treatment-related mortality or clinical signs of toxicity were observed.

- **Material-Mediated Pyrogenicity:**
  Evaluated in accordance with ISO 10993-11:2017 and USP <151> Pyrogen Test. No pyrogenic response was observed.

All testing met applicable acceptance criteria. No adverse biological responses were identified under the conditions of the studies. Collectively, these results demonstrate that the materials and manufacturing processes used in the device do not present unacceptable biological risks for its intended short-term mucosal contact.

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 [including AMD1:2023] and ISO 11607-2:2019 [including AMD1:2023], and ASTM F88/F88M-23, ASTM F1929-23.
   Transport and shipping testing as per ASTM D4169-22.

Summary of Clinical Tests

Clinical Tests Not Applicable.

Conclusion

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