December 18, 2025

Jiangsu Jiyuan Medical Technology Co., Ltd.
Yan Yao
Consultant
No. 48 CECEP (Taizhou) Environmental Protection Technology
Industry Park, No.59 Meilan Road
Taizhou, Jiangsu
CHINA

Re: K252793
Trade/Device Name: ARMI® Endoscopic Video Image Processor (JY-MIP-3000);
ARMI® Single-Use Hysteroscope (SH-01A, SH-02A, SH-03A, SH-04A, SH-05A, SH-01B, SH-02B, SH-03B, SH-04B, SH-01C, SH-02C, SH-03C, SH-04C)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: November 20, 2025
Received: November 20, 2025

Dear Yan Yao:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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,

Reginald K. Avery -S

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252793

Device Name
ARMI® Endoscopic Video Image Processor (JY-MIP-3000); ARMI® Single-Use Hysteroscope (SH-01A, SH-02A, SH-03A, SH-04A, SH-05A, SH-01B, SH-02B, SH-03B, SH-04B, SH-01C, SH-02C, SH-03C, SH-04C)

Indications for Use *(Describe)*
ARMI® Hysteroscopy System 2.0 is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative 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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510(k) Summary

1. Submitter Information

Applicant Name: Jiangsu Jiyuan Medical Technology Co., Ltd.

Applicant Address: No. 48 CECEP (Taizhou) Environmental Protection Technology Industry Park, No.59 Meilan Road Taizhou Jiangsu China

Contact Telephone: +86 13961010462

Office Number: 400-013-5066

Contact Person: Ms. Yan Yao

Contact Email: yaoy@jiyuanmedical.com

Date Prepared: December 15, 2025

2. Device Information

Device Trade Name: ARMI® Endoscopic Video Image Processor (JY-MIP-3000);

ARMI® Single-Use Hysteroscope (SH-01A, SH-02A, SH-03A, SH-04A, SH-05A, SH-01B, SH-02B, SH-03B, SH-04B, SH-01C, SH-02C, SH-03C, SH-04C)

Common Name: Hysteroscope and accessories

Regulation Name: Hysteroscope And Accessories

Regulation Number: 21 CFR 884.1690

Regulatory Class: Class II

Product Code(s): HIH

Panel: Obstetrics/Gynecology

3. Predicate Devices

K210270	Medical Endoscope Image Processing System

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

4. Device Description

The ARMI® Hysteroscopy System 2.0 (subject device) is a hysteroscope and compatible accessories consisting of the following components:

- ARMI® Endoscopic Video Image Processor (non-sterile, reusable),
  - JY-MIP-3000
- ARMI® Single-Use Hysteroscope (sterilized with ethylene oxide),
  - SH-01A, SH-02A, SH-03A, SH-04A, SH-05A, SH-01B, SH-02B, SH-03B, SH-04B, SH-01C, SH-02C, SH-03C, SH-04C
- Disposable Electronic Hysteroscope (sterilized with ethylene oxide) (510(k) cleared under K210270),
- Power cord and Power adapter (non-sterile, reusable),
- Hysteroscope cable (non-sterile, reusable), and
- HDMI cable (non-sterile, reusable) (optional)

Both hysteroscopes are single-use and the rest of the components are reusable.

The image processor is powered by an AC adapter (100 – 240V AC, 50/60 Hz) or battery (7.4V DC).

The subject device includes 13 models of the ARMI Single-Use Hysteroscope. The models have a working length of 245 mm. The models have different image resolutions, tip angles, insertion diameters, and instrument channel diameters.

Table 1. Specific Parameters for Different Models of ARMI® Single-Use Hysteroscope:

Model	Image Resolution	Angled shaft proximal to tip	Maximum Insertion Diameter(mm)	Minimum instrument channel(mm)
SH-01A	160,000 pixels	0°	3.0	/
SH-02A		0°	4.0	1.3
SH-03A		18°	5.0	1.9
SH-04A		22°	4.9	2.1
SH-05A		18°	6.5	3.1
SH-01B	640,000 pixels	0°	4.0	/
SH-02B		22°	5.0	1.7
SH-03B		15°	5.0	1.7
SH-04B		15°	6.5	3.1
SH-01C	1,000,000 pixels	0°	4.5	/
SH-02C		0°	5.0	1.7
SH-03C		22°	5.0	1.7

SH-04C		0°	6.5	3.1

The subject devices are noted to contain two different LED models (0301, 9653) and three different image sensors (ovm6946/ochsa10/ov9734).

Table 2: The specifications of the image sensor are shown in the table below:

Image sensor model	OVM6946	OCHSA10	OV9734
LED model	0301	9653	
Product Model	SH-01A, SH-02A, SH-03A, SH-04A, SH-05A	SH-01B, SH-02B, SH-03B, SH-04B	SH-01C, SH-02C, SH-03C, SH-04C
active array size	400 x 400	800 x 800	1280 x 720
exposure time（μs）	90-33000	90-33000	90-33000
sampling rate	30 fps	30 fps	30 fps
pixel size	1.75 μm x 1.75 μm	1.116 μm x 1.116 μm	1.4 μm x 1.4 μm
image area	714 μm x 707 μm	892 μm x 892 μm	1819.58 μm x 1033.34 μm

5. Indications for Use

ARMI® Hysteroscopy System 2.0 is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

The subject and predicate indications for use are the same, except for the device name.

6. Comparison of Technological Characteristics

The differences in technological characteristics do not raise different questions of safety and effectiveness.

Device & Predicate Device(s):	Subject Device (K252793)	Predicate Device (K210270)
Regulation	21 CFR 884.1690	21 CFR 884.1690
Product Code	HIH	HIH
System Components	Disposable Cannula and Image Processing System	Disposable Cannula and Image Processing System

Clinical Application	Diagnostic and Operative Hysteroscopy	Diagnostic and Operative Hysteroscopy
Scope Outer Diameter	3.0-6.5 mm	4.8 mm
Inner Diameter/Tool Size	1.3-3.1 mm	2 mm
Scope Working Length	245 mm	200 mm
Field of View	100°±10%	100º ±5º
Distal End Angle	0, 15, 18, or 22 º	16º
Light Source	2 LEDs	2 LEDs
Image Resolution	160,000 pixels 640,000 pixels 1,000,000 pixels	160,000 pixels
Disposable/Reusable	Cannula: Single-Use Image Processor: Reusable	Cannula: Disposable Image System: Reusable
Image Transmission	CMOS	CMOS
Image and Video Capture	Image and Video	Image and Video
Sterilization	Ethylene Oxide (EO)	EO

7. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and to support the substantial equivalence determination. The results demonstrated that the proposed device complies with all design requirement specifications or the following standards:

Bench Testing

The performance of the subject device is evaluated through the following tests:

- The optical safety and performance of the subject device is evaluated based on the following characteristics:
    - Photobiological safety
    - Field of view
    - Direction of view
    - Resolution
    - Effective depth of field range
    - Noise and dynamic range

  - Geometric distortion
  - Intensity uniformity
- The color performance is evaluated based on the raw data (CIEXYZ measurements), the captured images, and the FDA Color Performance Review (CPR) Tool one pager outputs.
- The mechanical performance is evaluated based on tensile strength, torque, stiffness, leakage, flow, and rotation testing.

Electrical Safety & EMC

- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-18:2009 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Battery Safety

- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Sterility

The ARMI Single-Use Hysteroscope is a single-use hysteroscope and sterilized with ethylene oxide (EO). The single use hysteroscope was validated per ISO 11135 (2014) using the overkill approach, the EO limit was validated per ISO 10993-7 (2008).

Packaging Integrity/simulated Shipping Distribution Validation

Transport validation of the devices is provided. The methods used in testing comply with the following standards:

- ASTM D4169 (2022) Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 11607-1 (2009) Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F1980 (2021) Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
- ASTM F88 (2023) Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D3078-02 (2021) Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ASTM F1929 (2023) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ISO 11737-2 (2019) Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ASTM F1886/F1886 (2016) Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- DIN 58953-6 (2023) Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized

Biocompatibility

The biocompatibility of the subject device is evaluated through the following tests in accordance with:

- Cytotoxicity (ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity)
- Sensitization- Guinea Pig Maximization Testing (ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization)

- Intracutaneous Reactivity (ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation)
- Vaginal Irritation (ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation)
- Acute Systemic Toxicity (ISO 10993- 11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity)
- Material-Mediated Pyrogenicity (ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity)

Software and Cybersecurity Validation

- Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's guidance, "*Content of Premarket Submissions for Device Software Functions.*" The document level is Basic.
- The cybersecurity was evaluated according to the FDA guidance "*Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions*"

8. Conclusions

The non-clinical performance data demonstrate that the subject device is as safe and effective as the predicate devices and support the subject device is substantially equivalent to the predicate device.