May 15, 2026

Suzhou AcuVu Medical Technology Co., Ltd.
Sam Mostafavi
Regulatory Affairs
B1-212, Bio-Nano Park, 218 Xinghu St.
Suzhou Industrial Park
Suzhou, Jiangsu, 215125
CHINA

Re: K254050
Trade/Device Name: Manual Tissue Removal Device
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: April 12, 2026
Received: April 13, 2026

Dear Sam Mostafavi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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)*
K254050

Device Name
Manual Tissue Removal Device

Indications for Use *(Describe)*
Manual Tissue Removal Device is intended for use to perform tissue resection and removal within uterine cavity, including focal lesions such as polyps and retained products of conception.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 – K254050

I. Submitter Information:

Manufacturer: Acuvu Medical (Suzhou AcuVu Medical Technology Co., Ltd./Acuvu Medical System)
B1-212, Bio-Nano Park, 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu, China 215125

Contact Person: Sam Mostafavi
Email: ipcs11@ymail.com
Mobile Number: 650-670-6972
Office Number: 650-578-9653
Facsimile Number: 650-578-9653

Date Prepared: May 14, 2026

II. Device Information:

Trade/Device Name: Manual Tissue Removal Device
Common/Usual Name: Hysteroscopic Tissue Removal Device
Regulation Number: 21 CFR § 884.1690
Regulation Name: Hysteroscope and accessories
Product Class: Class II
Product Code HIH
Panel: Obstetrics/Gynecology

III. Predicate Device:

MyoSure MANUAL Tissue Removal Device (K173901)
The predicate device has not been subject to a design-related recalls.

IV. Device Description

Manual Tissue Removal Device is designed for office, day surgery, and operating theater hysteroscopic procedures, providing a minimally invasive solution for removing intrauterine pathology such as polyps and retained products of conception. It is a single-use manual device without the need for electrical power. Continuous saline irrigation is maintained with a pressure bag or hanging bag, or a traditional pump. By utilizing a blade and lever, it enables precise tissue resection under direct visualization through AcuVu's compatible hysteroscopes.

The device consists of a cutting window, blade, shaft, rotation knob, tissue trap and cover, handle,

trigger and outflow tube. In addition, a configurable vacuum source is required to absorb the cut tissue and waste fluid. A removable tissue trap collects the cut tissue and the waste fluid is discharged through the outflow tube.

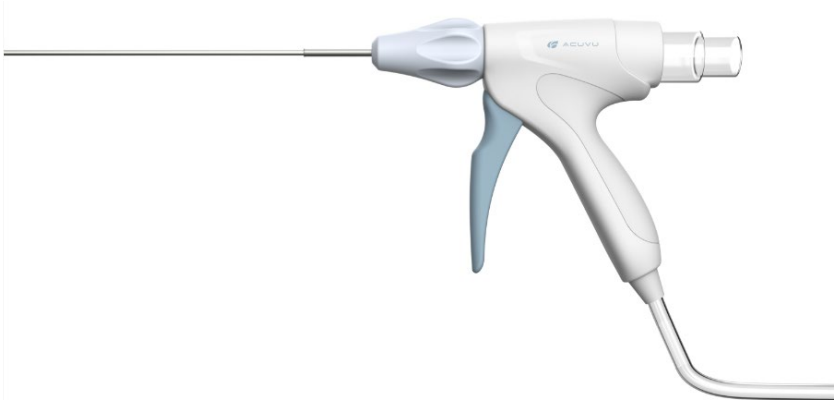

Figure 1 Manual Tissue Removal Device

The following models/dimensions are available for the subject device:

Model	Maximum insertion portion width	Working length
MTRD-9-370	3mm (9Fr)	370 mm
MTRD-9-325	3mm (9Fr)	325 mm

V. Indications for Use

Manual Tissue Removal Device is intended for use to perform tissue resection and removal within uterine cavity, including focal lesions such as polyps and retained products of conception.

The subject device intended use is identical to the predicate device.

VI. Comparison of Technological Characteristics

The subject and predicate device have similar technological characteristics, including design, materials, method of use and mode of operation, tissue resection mechanism, device markings and sterility.

	Subject Device Manual Tissue Removal Device (K254050)	**Primary Predicate MyoSure MANUAL Tissue Removal Device (K173901)**
Manufacturer	AcuVu	Hologic, Inc.
Classification	Class II	Class II
Regulation Number	21 CFR § 884.1690	21 CFR § 884.1690
Classification Panel	Obstetrics and Gynecology	Obstetrics and Gynecology
Product Code	HIH	HIH
Indications for Use	Intended for use to perform tissue resection and removal within the uterine cavity,	Intended for intrauterine use by a trained gynecologist to hysteroscopically resect and

	including focal lesions such as polyps and retained products of conception.	remove tissue, including focal lesions such as endometrial polyps and retained products of conception.
Site of Use	Physician offices or Operating room settings	Physician offices or Operating room settings
Intended Users	Trained gynecologist	Trained gynecologist
Single-use/Reuse	Single-use	Single-use
Device Components	Cutting window, shaft, adjustment knob, tissue trap and cover, handle, trigger, outflow tube; requires external vacuum source.	Cutting window, cutting window locator, distal tip locator, trigger, adjustment knob, tissue trap and cover, outflow tube, inflow tube set; hand-actuated vacuum.
Working Length	370 mm (MTRD-9-370); 325 mm (MTRD-9-325)	320 mm
Outer Diameter	3 mm	3 mm
Patient Contact Materials	Compliant with ISO 10993	Compliant with ISO 10993
Sterilization	EO	EO

The primary differences between the subject and the predicate device are as follows:

- The working length is 37cm/32.5cm for the subject device vs. 32cm for the predicate device.
- The subject device is connected to an external vacuum source, whereas the predicate device is comprised of a hand-actuated vacuum.
- The predicate device is provided with an inflow tubing set, whereas the subject device is not.

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

VII. Performance Data

Non-clinical tests were performed in accordance with the applicable requirements of the following areas. Verification and validation activities are performed to ensure that product performance meets design requirements.

Sterilization

The device is provided sterile via ethylene oxide sterilization. Sterilization validation was performed in accordance with ISO 11135:2014+A1:2018. Results demonstrated that the sterilization process achieves the required sterility assurance level and that sterility is maintained through the labeled shelf life.

Biocompatibility

The biocompatibility evaluation was conducted in accordance with the FDA guidance “Use of

International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1:

Evaluation and testing within a risk management process". Testing included:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-23:2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)
- Material Mediated Pyrogenicity (ISO 10993-11:2017)

The device was found to be non-cytotoxic, non-sensitizing, and non-irritating, with no evidence of acute systemic toxicity or pyrogenicity. These results demonstrate that extracts of the final, sterilized device do not result in unacceptable local or systemic biological responses under conditions representative of clinical use.

Performance Testing

Performance verification and validation testing of the Manual Tissue Removal Device evaluated the following:

- Visual Inspection
- Dimensional Measurements
- Rotation
- Tissue trap is removable
- Surface roughness
- Hardness
- Flow rate
- Cutting performance
- Mechanical robust
- Fitting performance
- Withstand repeated operation performance
- Compatibility between device and hysteroscope

All testing was conducted using defined acceptance criteria and applicable standards, and the results met acceptance criteria, demonstrating that the device performs as intended and maintains structural and functional integrity under foreseeable clinical use conditions.

VIII. Conclusion

Based on the information presented, the subject device has the same intended use and similar technological characteristics as the predicate device. Performance data provided in this submission

demonstrated that the Manual Tissue Removal Device performs as intended and supports a determination of substantial equivalence to the predicate device.