March 5, 2024

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

Re: K231260
Trade/Device Name: HTx Disposable Hysteroscope System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Received: January 30, 2024

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: 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.

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 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)*
K231260

Device Name

HTx Disposable Hysteroscope System

Indications for Use *(Describe)*
HTx Disposable Hysteroscope System is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves a method of surgery.

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.

510(k) Summary

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information:

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

Contact Person: Sam Mostafavi
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Office Number: 650-670-6972
Facsimile Number: 650-578-9653

Date Prepared: March 1, 2024

2. Device Information:

Trade/Device Name:	HTx Disposable Hysteroscope System
Common Name:	Hysteroscope
Model:	HTx1000 and HTx2000
Regulation Number:	21 CFR § 884.1690
Regulation Name:	Hysteroscope and accessories
Regulatory Class:	Class II
Product Code	HIH (Hysteroscope (And Accessories))
Panel:	Obstetrics/Gynecology

3. Predicate Device:

HTx Disposable Hysteroscope System (K211227). This predicate device has not been subject to a design-related or safety recall.

4. Device Description

The HTx Disposable Hysteroscope System is a single use hysteroscope endoscope intended for gynecology procedure applications. It includes a single-use, disposable hysteroscope cannula (HTx40 or HTx60), a reusable imaging system (HTx1000/Htx2000), and optional accessories (medical keyboard, barcode reader and IV pole mounting rack).

(a) HTx40/HTx60 hysteroscope

(b) HTx1000 image processor

(c) HTx2000 image processor

Figure 1: HTx Disposable Hysteroscope System

The disposable hysteroscopes (HTx40 or HTx60) were cleared under K211227. The disposable hysteroscope contains a miniature CMOS camera, a light-emitting diode (LED) illumination module, and channels for fluid in/out flow as well as for instrument insertion. HTx60 has a cannula outer diameter of 6.2 mm and adapts to tools up to 3 mm (9 Fr), while HTx40 has an outer diameter of 4.5 mm and adapts to tools up to 5 Fr. The cannula connects directly to the image processor via an image cable. The image processor processes the raw image signal from the cannula and outputs the video on a display for real-time visualization. The image processor includes input/output ports for interfacing with different peripherals such as a keyboard or a USB flash disk. Fluid irrigation is achieved through a tube which is connected to an IV bag and pressured via peristaltic pump (not included in the subject device). The fluid inflow channel shares the same channel with the working channel.

AcuVu has designed a new image processor HTx2000 as an alternative to the existing HTx1000 cleared under K211227 and modified HTx1000 since the clearance under K211227.

Changes made to the subject device compared to the predicate device are as follows:

- A new image processor, HTx2000, is added to the system as an alternative option to the existing HTx1000.
  - Portable
  - an external monitor is optional for display
    - HDMI port is available for an optional external monitor (2x DVI for HTx1000)
  - A new power source (Li-ion battery) is available in addition to an AC adapter.
  - Touch screen (no keyboard is needed)
  - Input interface: to connect the hysteroscope image cable and receive raw signal input, a 38-pin gold finger design (a 14-pin aviation socket for HTx2000)
  - LAN port is disabled
  - Software is revised for HTx2000 to incorporate the changes,
  - Polycarbonate/acrylonitrile, butadiene, styrene (PC/ABS) plastic housing material
- Design changes of HTx1000 since K211227 clearance
  - Magnetic ring: removed
  - Cable connector: a new connector of the hysteroscope and cable has been redesigned
  - Power cord: the power cord is changed
  - Power adapter: a new power adapter has been changed
  - ISP board: the image signal processor (ISP) board layout has been redesigned
  - An optional mounting rack is added as a new accessory for attaching the HTx2000 onto a metical IV pole.
  - Package and device labels are revised

The HTx2000 is a portable version of the HTx1000 in that it comes with a built-in touch screen, eliminating the necessity of attaching a keyboard and an external monitor as user interface for information entry and display.

The HTx2000 will not supersede the legally marketed HTx1000, but is an alternative option for users. The HTx1000 will continue to be available as a component of the HTx Disposable Hysteroscope System. The following table provides an overview of all key components of the subject device and explains which are

legacy modules inherited from the predicate device and which are newly developed ones.

Table 1: List of major components of the subject device

Component	Model	Manufacturer	Notes
Disposable hysteroscope	HTx40	AcuVu	Inherited from the predicate device
	HTx60	AcuVu	
Image processor	HTx1000	AcuVu	
	HTx2000	AcuVu	New item for submission

Table 2 below gives a comprehensive comparison between the existing HTx1000 and the newly developed HTx2000.

Table 2: HTx1000 versus HTx2000 image processor

	HTx1000	HTx2000
Appearance		
Compatible cannula	HTx40 HTx60	HTx40 HTx60
Power supply	100-240V AC	(1) 100-240V AC (2) Lithium battery
Peripheral interface	USB2.0×3 LAN×1 (disabled) DVI×2	USB2.0×2 LAN×1 (disabled) HDMI×1
Image display	External monitor	(1) 13.3” touch screen (2) External monitor
Main board	Model: E611	Model: E661
Operation software	IPC	UterView
Protection against Electrical shock	Class I	Class I
Dimension (L×W×H in mm)	365 × 262 × 144	324 × 203 × 46
Weight (Kg)	5.3	1.9

The subject device also offers optional accessories, as summarized in Table 3 below.

Table 3: List of accessories of the subject device

Accessory	Model	Manufacturer	Notes
Keyboard	KSI-U10200	Gett	Inherited from the predicate device and works with HTx1000 only.
Patient management software	PIMC	AcuVu	
Barcode scanner	14952	Deli	Inherited from the predicate device and works with both HTx1000 & HTx2000.
IV pole mounting rack	RD1851L20	AcuVu	Used to mount the HTx2000 onto a medical IV pole

Note:

a) The display (Jusha E240A) previously available as an optional accessory of the predicate device has now been removed from the accessory list of the subject device.

b) The IV pole mounting rack is a newly developed accessory for mounting the HTx2000 on an IV pole (see the drawings below).

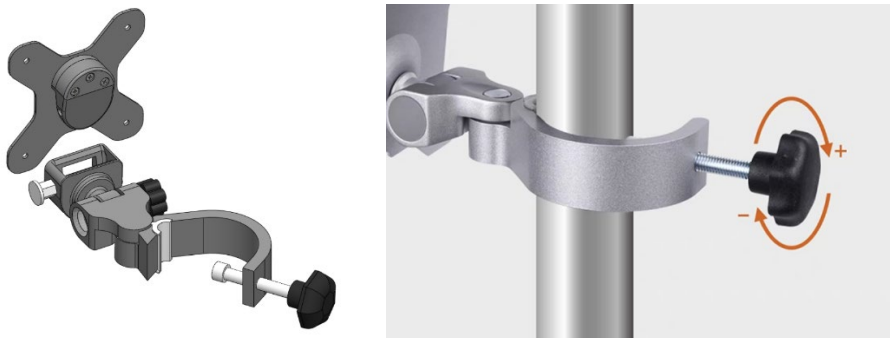

Figure 2: The IV pole mounting rack for HTx2000

5. Indications for Use

HTx disposable hysteroscope system is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves a method of surgery.

6. Comparison of Technological Characteristics

Table below includes functional and technological comparison between the subject device and predicate device.

Table 4: Functional and Technology substantial equivalency comparison

Feature	Subject Device	Predicate Device	Subject Device Comparison
	Suzhou AcuVu Medical Technology Co. Ltd. **HTx Disposable Hysteroscope System**	**Suzhou AcuVu Medical Technology Co. Ltd.** **HTx Disposable Hysteroscope System (**K211227**)**	
Classification	Class II	Class II	*Same as the predicate device*
Regulation Name	21 CFR § 884.1690	21 CFR § 884.1690	*Same as the predicate device*
Classification Panel	Obstetrics and Gynecology	Obstetrics and Gynecology	*Same as the predicate device*
Product code	HIH	HIH	*Same as the predicate device*
Indications for use	HTx disposable hysteroscope system is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures. Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves a method of surgery.	HTx disposable hysteroscope system is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.	*Same as the predicate device*
Procedures	Viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic or operative procedures	Viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic or operative procedures	*Same as the predicate device*
Environment of use	Hospitals and physician's office	Hospitals and physician's office	*Same as the predicate device*

Intended users	Trained Medical Professionals	Trained Medical Professionals	*Same as the predicate device*
Disposable/ Reusable	Cannula is single use; The image processor and other modules are reusable	Cannula is single use; The image processor and other modules are reusable	*Same as the predicate device*
Sterilization	Cannula is provided sterile; The image processor and other modules are provided non-sterile.	Cannula is provided sterile; The image processor and other modules are provided non-sterile.	*Same as the predicate device*
Clinical application	Diagnostic and operative hysteroscopy.	Diagnostic and operative hysteroscopy.	*Same as the predicate device*
Patient contacting materials (Biocompatibility)	ISO 10993 compliant	ISO 10993 compliant	*Same as the predicate device*
Components: - cannula	(1) HTx40 hysteroscope (2) HTx60 hysteroscope	(1) HTx40 hysteroscope (2) HTx60 hysteroscope	*Same as the predicate device*
Components: - image processor	HTx1000 image processor HTx2000 image processor	HTx1000 image processor	*Different.* *Subject device offers a second image processor HTx2000, but the difference does not raise different questions of safety and effectiveness for the device.*
Accessories	HTx1000: a barcode scanner or keyboard can be connected through USB interfaces HTx2000: a barcode scanner and an IV pole mounting rack	HTx1000: a barcode scanner or keyboard can be connected through USB interfaces, a medical-grade display (Jusha E240A)	*Different.*
AC power supply	100-240V AC converted to 12V DC by a power adapter	100-240V AC converted to 12V DC by a power adapter	*Same as the predicate device*
Battery-powered mode	Yes (HTx2000)	No	*Different.* *The HTx2000 image processor of the subject device can also be powered by batteries. The difference does not raise different questions of safety and effectiveness for the device.*

Mode of operation	Continuous video	Continuous video	*Same as the predicate device*
Cannula outer diameter	4.5mm-6.2mm	4.5mm-6.2mm	*Same as the predicate device*
Cannula length	Working length: 240 mm Overall length: 330 mm	Working length: 240 mm Overall length: 330 mm	*Same as the predicate device*
Field of view and direction of view	FOV: >115°, DOV: 12° (HTx60) and 8° (HTx40)	FOV: >115°, DOV: 12° (HTx60) and 8° (HTx40)	*Same as the predicate device*
Light source	LEDs at cannula tip	LEDs at cannula tip	*Same as the predicate device*
Image sensor	CMOS sensor 400 x 400 pixels	CMOS sensor 400 x 400 pixels	*Same as the predicate device*
Image cable connection	(1) Cable with 38-pin gold-finger connector (for HTx2000) (2) Cable with 14-pin aviation connector (for HTx1000)	Cable with 14-pin aviation connector (for HTx1000)	*Different.* *The HTx2000 image processor uses an image cable with 38-pin gold-finger connector. This difference does not raise different questions of safety or effectiveness for the device.*
Connectivity to customer computer	No (for HTx2000) Yes (for HTx1000)	Yes (for HTx1000)	*Different.* *The LAN port on HTx2000 image processor is currently disabled for any connection to external computer or network, which mitigates cyber security risks when compared to HTx1000.*
Live video output port	(1) HDMI (for HTx2000) (2) DVI (for HTx1000)	DVI	*Different.* *The HTx2000 image processor uses an HDMI rather than DVI port for video output. This difference does not raise different questions of safety or effectiveness for the device.*

Built-in touch screen	Yes (for HTx2000)	No	*Different.* *The HTx2000 image processor has a touch screen for both displaying and user input. This difference does not raise different questions of safety or effectiveness for the device.*
Adjust brightness of LEDs during procedure	By pressing a LED button on the cannula	By pressing a LED button on the cannula	*Same as the predicate device*
Capture image or video during procedure	By pressing a camera button on the cannula	By pressing a camera button on the cannula	*Same as the predicate device*
Shelf life	≥ 2 years (cannula) ≥ 5 years (image processor)	≥ 2 years (cannula) ≥ 5 years (image processor)	*Same as the predicate device*
Operation software	IPC (for HTx1000): accepts user input via panel buttons or keyboard. UterView (for HTx2000): accepts user input via the touch screen.	IPC (for HTx1000): accepts user input via panel buttons or keyboard.	*Different.* *The HTx2000 software is more suited for touch screen operation and is renamed as UterView. This difference does not raise different questions of safety or effectiveness for the device.*

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

7. Summary of Non-clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. No additional testing for HTx40 or HTx60 alone were necessary. However, the hysteroscope's compatibility with the image processors was assessed. The results demonstrated compliance with all design requirement specifications or statutory standards.

a) Bench-top test

1) Color performance for HTx2000 utilizing the HTx40 and HTx 60 hysteroscopes assess the following specifications:

a) Ground truth measurements using a spectrophotometer

b) Working distance

c) color contrast enhancement (CCE)

2) Basic electric safety (electrical, thermal, mechanical, etc.)

IEC 60601-1:2005+AMD1:2012 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.

3) Electromagnetic compatibility

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.

4) Software testing

The software of the subject device was validated as Basic Documentation Level in accordance with FDA's Guidance for Industry and FDA Staff, *"Content of Premarket Submissions for Device Software Functions"*, issued on June 14, 2023.

5) Battery safety

The lithium-ion battery safety was verified in compliance with the applicable requirements of IEC 62133-2:2017/AMD1:2021 and UN38.3.

8. Conclusions

The performance testing summarized above support that the subject device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.