September 15, 2021

AcuVu, Inc.
Sam Mostafavi
Regulatory Affairs
4546 El Camino Real #211
Los Altos, CA 94022

Re: K211227
Trade/Device Name: HTx Disposable Hysteroscope System
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: August 10, 2021
Received: August 12, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211227

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.

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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510(k) Summary

510(k) Number: K211227

Applicant Information:

Date Prepared:	September 10, 2021
Manufacturer:	AcuVu Inc. 4546 El Camino Real #211 Los Altos, CA 94022
Contact Person:	Sam Mostafavi ipcs11@ymail.com
Mobile Number:	650-670-6972
Office Number:	650-578-9653
Facsimile Number:	650-578-9653

Device Information:

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

Predicate Device:

AcuVu GDT-1000 (K180096)

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

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.

Device Description

The HTx Disposable Hysteroscope System is a single use hysteroscope endoscope intended for gynecology procedure applications. It includes a disposable cannula module, a reusable imaging system, a medical grade display and optional software for processing patient management.

The disposable cannula contains a miniature complementary metal–oxide–semiconductor (CMOS) camera, a light-emitting diode (LED) illumination module, and a channel for fluid and device. The cannula connects directly to the image system via an image cable. The cannula also contains three (3) buttons for video recording, picture taking, and light-emitting diode (LED)

brightness control. The image system connects to a medical grade display module via DVI port. The external patient management software runs on an external PC that connects with the image system via LAN cable.

Disposable Cannula

The disposable cannula module family includes two models. HTx60 has an outer diameter of 6.2mm and adapts to tools up to 3mm, and HTx40 has an outer diameter of 4.5mm and adapts to tools up to 5Fr. The disposable single-use cannula contains a miniature camera module and an LED illumination module at the tip. The cannula connects to the image system through an image cable for image data transfer, camera control, and power supply.

The disposable cannula has a working length of 240mm, and an overall length is 330mm.

Fluid irrigation is achieved through a tube which is connected to an IV bag and pressured via peristaltic pump. The disposable cannula is sterilized and packaged in a sealed pouch.

Image System Module

The HTx1000 image system Module is reusable. It connects to the disposable cannula through an image cable. Its proximal end has a USB connection interface and power button. It contains the image processing controller and user interface software to check the live video during the procedure.

The Image System Module contains several function buttons for use during a procedure – an LED adjustment button to adjust brightness, an information retrieve button to review the stored images, and a set of navigation buttons to instruct the user on setting functions.

Functional and Technological Comparison

Table below includes a functional and technological comparison between AcuVu HTx System and AcuVu GDT-1000 System (K180096).

Table-1: Functional and Technological Comparison

Feature	Subject Device	Predicate Device	Comparison
	AcuVu Inc. Inc. HTx Disposable Hysteroscope System	**AcuVu Inc. GDT-1000 System (K180096)**	
Classification	Class II	Class II	*Same*
Regulation Name	21 CFR § 884.1690	21 CFR § 884.1690	*Same*
Product code	HIH	HIH	*Same*
Indications for use	The HTx disposable hysteroscope system is intended to permit viewing of the cervical canal and uterine cavity for the purpose of performing	AcuVu GDT-1000 System is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of	*Same*

	diagnostic and operative procedure.	performing diagnostic and operative procedure.	
Site of use	Hospitals and physician's office.	Hospitals and physician's office.	*Same*
Intended users	Trained Medical Professionals.	Trained Medical Professionals.	*Same*
Device Features: Components	(1) image-capturing system and display; (2) attachable and disposable cannula with inflow and outflow ports.	(1) image-capturing hand piece and tower; (2) attachable cannula configuration with inflow and outflow ports.	*Different technology; similar performance*
Cannula outer diameter	4.5mm-6.2mm	4.8 – 5.3 mm (operative) 4.8 – 5.3 mm (diagnostic)	*Similar to predicate device*
Cannula length	Working length: 240 mm Overall length: 330 mm	Working length: 220 – 240 mm Overall length: 300 - 350 mm	*Similar; within range of predicate*
Illumination light source	LEDs	LEDs	*Same*
Image resolution	The CMOS sensor consists of 400 x 400 (160,000) pixels.	The CMOS sensor consists of 400 x 400 (160,000) pixels.	*Same*
Optical image	Digital CMOS	Digital CMOS	*Same*
Disposable/ Reusable	Cannula is provided sterile for single use and the image system and the monitor is reusable	Cannula is provided sterile for single use and the handle and tower is reusable.	*Same*
Battery operated	No	No	*Same*
Duration of use	< 24 hours	< 24 hours	*Same*
Field of View and Direction of Viewing	FOV>115 degrees, DOV: HTx 60: 12 Degrees HTx40: 8 degrees	FOV>115 degrees, DOV 0 degree	*Same FOV Different DOV*

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

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 productperformance meets design requirements.

Sterilization
The device is provided sterile via ethylene oxide sterilization. Sterilization validation was performed in accordance with ISO 11135:2014.

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 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)
- Material Mediated Pyrogenicity (ISO 10993-11:2017)

The results of testing demonstrated the subject device is non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, and non-pyrogenetic.

Electromagnetic Compatibility/Electrical Safety
The device was tested and found to be compliant with the following standards for electrical safety and EMC: IEC 60601-1, IEC 60601-2-18, and IEC 60601-1-2

Performance Testing
Optical performance (direction of view, field of view, distortion/resolution, luminous flux, color performance, photobiological safety), optical safety, and thermal safety testing were conducted in accordance with the standards listed below:

- ISO 8600-1:2015 Medical endoscopes and endotherapy devices – Part 1: General requirements
- ISO 8600-3:2019 Medical endoscopes and endotherapy devices – Part 3: Determination of Field of View and Direction of View of Endoscopes with Optics
- IEC 62471:2006 (First Edition) Photobiological safety of lamps and lamp systems
- IEC 60601-2-18:2009 Medical electrical equipment, Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Software
Software documentation for a Moderate Level of Concern device is provided in support of the subject device per FDA's 2005 *Guidance for the Content of Premarket Submissions for Software Contained in Medical Device*.

Conclusion:

The performance testing summarized above support a substantial equivalence determination. The performance testing demonstrates that the subject device is as safe and as effective as the legally marketed predicate device