November 23, 2021

Hysterovue, Inc.
Thomas Lawson, Ph.D.
Vice President, Regulatory Affairs
5337 14th Place SE
Bellevue, WA 98006

Re: K202445
Trade/Device Name: Hystero-V Hysteroscope
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH, HFF
Dated: October 22, 2021
Received: October 25, 2021

Dear Thomas Lawson:

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 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)*
K202445

Device Name
Hystero-V Hysteroscope

Indications for Use *(Describe)*
The Hystero-V hysteroscope is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy) in an outpatient or office setting. The sample is used for cytologic and histologic diagnosis. Generally recognized indications for diagnostic hysteroscopy include abnormal uterine bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

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

General Information

Submitter	Hysterovue, Inc.
Address	Hysterovue, Inc. 5337 14th Place SE Bellevue, WA 98006
510k Number	K202445
Correspondence Person	Thomas Lawson, PhD
Contact Information	Email: drthomlawson@gmail.com Phone: 510-206-1794
Date Prepared	19 November 2021

Proposed Device

Trade Name	Hystero-V Hysteroscope
Common Name	Hysteroscope
Regulation Number and Classification Name	21 CFR§884.1690, Hysteroscope and Accessories 21 CFR§884.4530, Obstetric-Gynecologic Specialized Manual Instrument
Product Code	HIH, HHF
Regulatory Class	II

Predicate Device

Trade Name	U-Scope 8000 HSC+EMB Cannula Hysteroscope
Common Name	Hysteroscope
Premarket Notification	K132384
Regulation Number and Classification Name	21 CFR§884.1690, Hysteroscope and Accessories
Product Code	HIH
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Reference Device

Trade Name	Uro-V Cystoscope
Common Name	Cystoscope
Premarket Notification	K171500
Regulation Number and Classification Name	21 CFR§884.1500, Endoscope and Accessories
Product Code	FAJ
Regulatory Class	II
Note: This device has not been subject to a design-related recall.	

Device Description

The Hystero-V hysteroscope is a handheld, battery operated portable hysteroscope consisting of a sterile, single-use cannula and a reusable handle with an LCD touchscreen monitor. It is intended to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and endometrial tissue sample (biopsy) in an outpatient or office setting. The disposable cannula has a light source and camera at the distal end that are used for visualization and to capture image and video of the diagnostic area. The image and video signals are transferred electronically from the cannula to the monitor on the handle via an electrical connection so that the physician can view the anatomy during the procedure. The cannula also has a fluid channel that can infuse fluids during the procedure or evacuate tissue. The fully assembled Hystero-V hysteroscope has an overall length of 465 mm (18.3 inches); the working length of the disposable cannula component is 254 mm (10 inches). When assembled, the Hystero-V hysteroscope weighs 0.5 pounds. The materials used in construction of the cannula—stainless steel, nylon, and polycarbonate—contact tissue for less than 24 hours. The device has been tested for biocompatibility and was shown to be biocompatible. The handle does not contact the patient.

Indications for Use

The indications for use for the Hystero-V hysteroscope are:

> The Hystero-V hysteroscope is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy) in an outpatient or office setting. The sample is used for cytologic and histologic diagnosis. Generally recognized indications for diagnostic hysteroscopy include abnormal uterine bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

The Hystero-V hysteroscope has equivalent intended use and indications for use statement as the U-Scope 8000 HSC+EMB, *i.e.*, viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and facilitating endometrial sample (biopsy).

Comparison of Technological Characteristics with the Predicate Device

Hysterovue, Inc. has identified the U-Scope 8000 HSC hysteroscope +EMB Cannula (EndoSee Corp., K132384) as the predicate device. The Uro-V cystoscope (UroViu Corp., K171500) is a reference device. The Hystero-V hysteroscope is equivalent to the U-Scope 8000 HSC+EMB Cannula in terms of intended use, cannula tip configuration to facilitate tissue collection, and EM compatibility and safety. The Hystero-V hysteroscope is identical to the Uro-V cystoscope in terms of shape of the handle, materials used in its construction, biocompatibility of materials, sterilization method, packaging, and software.

Comparison of the Hystero-V hysteroscope (subject device) to the U-Scope 8000 HSC+EMB Cannula (predicate device) and the Uro-V cystoscope (reference device).

	Subject Device Hystero-V hysteroscope Hysterovue, Inc. (This Submission)	Predicate device U-Scope 8000 HSC+EMB EndoSee Corp. (K132384)	Reference Device Uro-V disposable cystoscope UroViu Corp. (K171500)
Indication for use	To permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial sample (biopsy) in an outpatient or an office setting. The sample is used for cytologic and histologic diagnosis.	To permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial sample (biopsy) in an outpatient or an office setting. Generally recognized indications for	For endoscopic diagnosis and treatment within the bladder and urethra.

	Generally recognized indications for diagnostic hysteroscopy include abnormal uterine bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, pelvic pain.	diagnostic hysteroscopy include abnormal uterine bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, pelvic pain.	
Intended Use	Viewing of cervical canal and uterine cavity and obtaining tissue samples	Viewing of cervical canal and uterine cavity and obtaining tissue samples	Endoscopic diagnosis and treatment within the bladder and urethra.
Route of Advancement	Advanced to uterine cavity via the cervical canal	Advanced to uterine cavity via the cervical canal	Advanced to the bladder via the urethra
Site of use	Hospitals and physician offices	Same	Same
Device Features			
Components	Reusable handle with video screen Attachable cannula with a working channel along its length and an illumination source and camera at its tip	Same Same	Same Same
Cannula Outer Diameter	4.25 mm	4.3 mm	3.9 mm
Cannula Total Length	254 mm	276 mm	254 mm
Illumination light source	LEDs	Same	Same
Image transmission	Image transmitted from a video camera at the tip of the cannula to a video monitor on the handle	Same	Same

LCD display size	3.5 inches (diagonal) on the handle	Same	Same
Field of View	140 degrees	120 degrees	140 degrees
Focal Length	5 to 50 mm	5 to 50 mm	5 to 25 mm
Direction of View from Center Axis	30 degrees	20 degrees	30 degrees
Adjust brightness of illumination	Adjust by depressing a button on the handle to change settings	Same	Same
Capture still images or video images during the procedure	Capture still images or video during procedure by depressing a camera button on the handle	Same	Same
Duration of use	≤ 24 hours	Same	Same
Sterilization	The handle is not provided sterile. The handle is cleaned and disinfected following company instructions. Disposable cannula is sterile following exposure to ethylene oxide (EO) and is single use; it is disposed after the procedure following the institution's procedures.	Same Same	Same Same
Frequency of use	Handle is reusable. Cannula is single patient use.	Same Same	Same Same
Tissue contact materials	Compliant with ISO 10993	Same	Same

Non-Clinical Performance Testing

Biocompatibility testing

The cannula of the Hystero-V hysteroscope is the only part that is in contact with the patient. The cannula is an externally communicating device with limited contact duration

(≤ 24 hours). Therefore, following ISO 10993-1:2018, the applicable biocompatibility tests are:

1. Cytotoxicity Test 10993-5:2009;
2. Irritation Test 10993-10:2010;
3. Guinea Pig Maximization Sensitization Test 10993-10:2010; and
4. Systemic Toxicity Study 10993-11:2006.

The cannula materials are identical to those used in the cannula of the Uro-V cystoscope reference device that was reviewed and cleared in K17500. In addition, the subject device has identical manufacturing and processing (including sterilization). Therefore, biocompatibility test data (as outlined in above) can be leveraged from K17500 to support the biocompatibility of the subject device.

Electrical safety and electromagnetic compatibility (EMC)

The subject device was evaluated for electrical safety and EMC and found to comply with IEC 60601-1 and IEC 60601-1-2 respectively.

Software testing

The software version running the Hystero-V hysteroscope is the same as that which runs the Uro-V cystoscope (reviewed and cleared in K171500), with the minor difference that "Hystero-V" and "Hysterovue, Inc." logos are shown on the screen when the device is powered up. As with the Uro-V cystoscope, according to the FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, the software for this device is considered to have a "moderate" level of concern. The software was validated and verified.

Mechanical Testing

The mechanical testing of the subject device included:

- Thermal safety of the light source on the distal tip of the cannula meets requirements specified in IEC 60601-2-18;
- Bending test demonstrated that attaching a weight to the cannula to bend it resulted in no mechanical damage to the cannula or degradation of imaging;
- Flow testing demonstrated no leaks from the working channel in the cannula when flow was set at 120 mL/min at a pressure of 300 mmHg;
- Image quality met requirements of ISO 8600-5;
- Field of view and Direction of Viewing accuracy met requirements of ISO 8600-3;

- Torque testing of the cannula demonstrated that image quality still met product specification after twisting the cannula and that no damage was visible to the cannula; and
- Pull testing of the cannula with two pounds of force did not compromise the image quality or damage the cannula.

Animal Testing

No preclinical testing of the subject device was necessary. The bench tests are sufficient.

Clinical Studies

No clinical testing of the subject device was necessary. The bench tests are sufficient.

Conclusion

The Hystero-V hysteroscope indications for use and technology do not raise no different questions of safety and effectiveness as compared to the predicate device. Performance testing demonstrated that the Hystero-V hysteroscope is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.