July 26, 2024

OriGyn Medical Technology (Hangzhou) Co., Ltd.
% Chen Yuling
Official Correspondent
Linnwell International Certification Consulting Co., Ltd.
First Floor, Building 1, No. 333 Wanfang Road,
Minhang District
Shanghai, 201112
CHINA

Re: K240401
Trade/Device Name: ClearVision Single Use Hysteroscope & Image Processing System (EHS-Dx4001, EHS-Op5001, EHS-Op6001, EHS-IPS01US)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Received: July 2, 2024

Dear Chen Yuling:

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 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)*
K240401

Device Name
ClearVision Single Use Hysteroscope & Image Processing System (EHS-Dx4001, EHS-Op5001, EHS-Op6001, EHS-IPS01US)

Indications for Use *(Describe)*
ClearVision Single Use Hysteroscope & Image Processing System is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures (EHS-Dx4001) or diagnostic and operative procedures (EHS-Op5001 and EHS-Op6001).

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

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

1.Submitter Information

Manufacturer	OriGyn Medical Technology (Hangzhou) Co., Ltd. 688 Bin'An Road, Building 6, Room 310, Hangzhou, Zhejiang Province China
Contact Person	Yuling Chen Linnwell International Certification Consulting Co., Ltd. Email: Yuling.chen@linnwell.com Phone: +86 15021397762
Date Prepared	July 26, 2024

2.Device Information

Trade/Device Name	ClearVision Single Use Hysteroscope & Image Processing System (EHS-Dx4001, EHS-Op5001, EHS-Op6001, EHS-IPS01US)
Proprietary Name	Medical Endoscope Image Processing System
Models	EHS-Dx4001, EHS-Op5001, EHS-Op6001 and EHS-IPS01US
Regulation Number	21 CFR 884.1690
Regulation Name	Hysteroscope and accessories
Product Code	HIH (Hysteroscope (And Accessories))
Regulatory Class	II
Panel	Obstetrics/Gynecology

3.Predicate Device

Predicate Device	HTx Single Use Hysteroscope System (K211227)
Legal Manufacturer	Acuvu Humming Scope

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

4.Indications for Use

ClearVision Single Use Hysteroscope & Image Processing System is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures (EHS-Dx4001) or diagnostic and operative procedures (EHS-Op5001 and

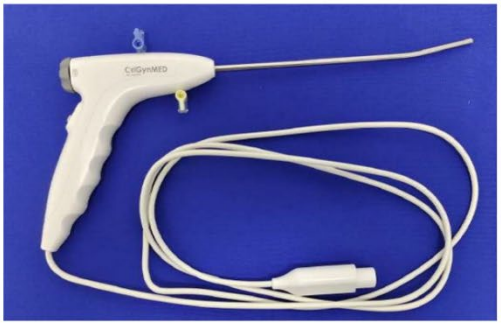
EHS-Op6001).

5.Device Description

ClearVision Single Use Hysteroscope & Image Processing System is a portable hysteroscope. It includes a sterile single use disposable electronic hysteroscope and a reusable Medical Endoscope Image Processor. The Disposable Electronic Hysteroscope contains a miniature CMOS camera and a light-emitting diode (LED) illumination module at its tip and two channels for infusion of irrigating fluid and aspiration of fluid and debris. The Disposable Electronic Hysteroscope is sterilized by ethylene oxide and is packaged in a sealed pouch with a shelf-life of one year.

The Medical Endoscope Image Processor contains a control panel with buttons, a video processor, microcontrollers, software and firmware. The equipment is powered by mains supply with a detachable power cord.

ClearVision Single Use Hysteroscope



Accessories : Power cord and HDMI cable

length：2.1m

length：1.7m

Image Processing system: Front and Back panel

The Hysteroscope comes in three models: EHS-Dx4001, EHS-Op5001 and EHS-Op6001 and the specifications are shown as below:

Model Number	EHS-Dx4001	EHS-Op5001	EHS-Op6001
Maximum insertion portion width	4.1 mm	5.1 mm	6.4 mm
Minimum instrument channel width	N/A	2.0 mm	3.3 mm
Tip bending angle	10°		0°
Direction of view	10°		0°
Field of view	120°		
Working length	200 mm		
Depth of field	~5 mm to 50 mm		

The EHS-Dx4001 model is intended to be used for performing only diagnostic procedures and EHS-Op5001 and EHS-Op6001 are used for both diagnostic and operative procedures.

6.Principles of Operation

The CMOS sensor at the tip of the Single Use hysteroscope converts the reflected light from the tissue into electrical signals. These signals are then transmitted through a cable connected to the image processing system. The image processing system converts the electrical signal into a video output to display on a connected monitor.

7.Comparison of technological characteristics to predicate device

Feature	Subject Device	Predicate Device	Comparison
	K240401 **OriGyn Medical Technology (Hangzhou) Co.,Ltd**	**K211227** **Suzhou Acu-Vu Medical Technology Co., Ltd.**	
Device Name	ClearVision Single Use Hysteroscope & Image Processing System	HTx Disposable Hysteroscope System	N/A
Regulation	21 CFR 884.1690	21 CFR 884.1690	Same
Product code	HIH	HIH	Same
Indications for use	ClearVision Single Use Hysteroscope & Image Processing System is intended to be used for viewing of the cervical canal and uterine cavity for the	HTx disposable hysteroscope system is intended to be used for viewing of the cervical canal and uterine cavity for the purpose of	Same

Feature	Subject Device	Predicate Device	Comparison
	K240401 **OriGyn Medical Technology (Hangzhou) Co.,Ltd**	**K211227** **Suzhou Acu-Vu Medical Technology Co., Ltd.**	
	purpose of performing diagnostic procedures (EHS-Dx4001) or diagnostic and operative procedures (EHS-Op5001 and EHS-Op6001).	performing diagnostic and operative procedures.	
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
Environment of use	Hospitals and physician's office	Hospitals and physician's office	Same
Intended users	Trained Medical Professionals	Trained Medical Professionals	Same
System Components	Disposable Cannula and Image Capture System	Disposable Cannula and Image Capture System	Same
Sterilization	Cannula is provided sterile (Ethylene Oxide). The image processor and other modules are provided non-sterile.	Cannula is provided sterile (Ethylene Oxide). The image processor and other modules are provided non-sterile.	Same
Clinical Application	Diagnostic and Operative Hysteroscopy	Diagnostic and Operative Hysteroscopy	Same
Scope Outer Diameter	EHS-Dx4001: 4.1 +0/-5% mm EHS-Op5001 : 5.1 +0/-5% mm EHS-Op6001: 6.4 +0/-5% mm	4.5mm (HTx40) 6.2mm (HTx60)	Different * See Note 1
Inner Diameter/Tool Size	5 Fr (EHS-Op5001) 9 Fr (EHS-Op6001)	5 Fr (HTx40) 9 Fr (HTx60)	Same
Scope Working Length	200 mm	240 mm Overall: 330 mm	Different * See Note 2
Field of View	120°	>115º	Different * See Note 3
Direction of View	EHS-Dx4001 : 10° EHS-Op5001 : 10° EHS-Op6001 : 0°	HTx60: 12º HTx40: 8º	Different * See Note 4
Light Source	LEDs at cannula tip	LEDs at cannula tip	Same

Feature	Subject Device	Predicate Device	Comparison
	K240401 **OriGyn Medical Technology (Hangzhou) Co.,Ltd**	**K211227** **Suzhou Acu-Vu Medical Technology Co., Ltd.**	
Image Resolution	1280 x 720 pixels	400 x 400 pixels	Different * See Note 5
Disposable/Reusable	Cannula/Hysteroscope: Disposable Image System: Reusable	Cannula/Hysteroscope: Disposable Image System: Reusable	Same
Image Transmission	CMOS	CMOS	Same
LCD Display Size	19-24 inches, any medical grade HD monitor.	24 inches	Different *See Note 5
Image and Video Capture	Image and Video	Image and Video	Same
Battery- powered mode	No	No	Same

Note 1: The outer diameter of the EHS-Dx4001 and EHS-Dx6001 is within the range of the predicate device. The difference does not raise different questions of safety and effectiveness.

Note 2: Shorter scope working length and does not raise different questions of safety and effectiveness.

Note 3: The field of view is (120 º) is within the range of the predicate device does not raise different questions of safety and effectiveness.

Note 4: The subject device has a direction of view of 10º for the two models, which is different than the predicate, but it is consistent with previously cleared devices and does not raise different questions of safety or effectiveness for the device.

Note 5: The subject device is recommended to be used with a medical grade HD monitor with similar LCD display size range as predicate and with a higher pixel resolution and does not raise different questions of safety and effectiveness.

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

8.Summary of Non-Clinical Performance Testing

The following performance data were provided to support substantial equivalence to the predicate

device.

8.1 Electrical Safety and Performance testing

The ClearVision Single Use Hysteroscope & Image Processing System was tested according to ES60601-1 and IEC 60601-2-18. The Safety and Performance results meet the requirements.

- ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)];
- IEC 60601-2-18 Medical electrical equipment - Part 2-18:2009 Particular requirements for the basic safety and essential performance of endoscopic equipment.

8.2 EMC testing

The ClearVision Single Use Hysteroscope & Image Processing System has been tested on according to IEC 60601-1-2. The EMC performance meets or exceeds the IEC 60601-1-2 requirements.

- IEC 60601-1-2:2020 General requirements for basic safety and essential performance-Collateral standard: Electromagnetic Disturbances-Requirements and tests.

8.3 Packaging verification

ClearVision Single Use Hysteroscope is individually packaged in a sterile package, which consists of a blister box and a Tyvek film.

Package Integrity testing included visual inspection, seal strength and dye penetration testing per the standards as below:

- *ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
- *ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems*
- *ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*

- *ASTM F1929-2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- *ASTM F88/F88M-2021, Standard Test Method for Seal Strength of Flexible Barrier Materials*

The transportation testing was conducted in accordance with ASTM D4169-22 (DC 13 – Level II) and accelerated aging per ASTM F1980-21 to support a 1-year shelf-life.

8.4 Sterilization Validation

The ClearVision Single-Use Hysteroscope was sterilized using Ethylene Oxide and validated according to the following applicable standards:

- *ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices*
- *ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods part 2: Tests of sterility performed in the validation of a sterilization process*
- *ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals*

Reprocessing of the image processor was conducted per *AAMI TIR30, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*.

8.5 Optical performance and mechanical performance test

The proposed system underwent testing for mechanical and optical performance listed in the table according to the standards listed below. The results indicate that the system meets the associated acceptance criteria and provides performance equivalent the Predicate Device.

Test category	**Test Item**
Optical and color performance	• Photobiological safety • Field of view • Direction of view • Resolution • Depth of field • Noise and dynamic range • Geometric distortion • Image intensity uniformity
Mechanical Performance	• Bending strength

Test category	Test Item
	• Tensile test • Function knob • Water tightness • Leakage • Flow

Standards used:

- *Hysteroscopes and Gynecologic Laparoscopes Submission Guidance for a 510(k)；March 7, 1996*
- *ISO 8600-1 Fourth Edition 2015-10-15 Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements*
- *ISO 8600-3:2019 Endoscopes — Medical endoscopes and endotherapy devices — Part 3: Determination of field of view and direction of view of endoscopes with optics*
- *ISO 8600-4:2014 Endoscopes — Medical endoscopes and endotherapy devices — Part 4: Determination of maximum width of insertion portion*
- *ISO 8600-5:2020 Optics and photonics — Medical endoscopes and endotherapy devices — Part 5: Determination of optical resolution of rigid endoscopes with optics*
- *ISO 15739:2017 Photography-Electronic still-picture imaging -noise measurements*
- *ISO 12233-2017 Photography-Electronic still picture imaging-Resolution and Spatial frequency responses*
- *IEC 62471：2006 Photobiological safety of lamps and lamp systems*

8.6 Shelf life

After 1 year of accelerated aging, the EHS-Dx4001、EHS-Op5001、and EHS-Op6001 Single Use hysteroscopes meet design input and packaging requirements for sterile barrier systems as outlined in the associated standards. The shelf life for the single use hysteroscopes is set at 1 year.

The EHS-IPS01US Image Processing System underwent accelerated aging in accordance with ASTM F1980-21 to validate its performance for a shelf life of 5 years.

- *ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

8.7 Biocompatibility testing

The product was tested for cytotoxicity, acute toxicity, pyrogenicity, sensitization, and intracutaneous irritation in accordance with the FDA guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process'" and a device with limited (<24 hours) contact with breached or compromised tissue. The results demonstrate that the product's biocompatibility meets the required criteria. The following standards were used to complete the testing:

- *ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- *ISO 10993-2:2022 Biological evaluation of medical devices-Part 2: Animal welfare requirements*
- *ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- *ISO 10993-12:2021Biological evaluation of medical devices-Part 12: Sample preparation and reference materials*
- *ISO 10993-10:2021 Biological evaluation of medical devices-Part 10: Tests for skin sensitization*
- *ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Tests for irritation*
- *ISO 10993-11: 2017 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity & material mediated pyrogenicity*

The test results demonstrate that the subject device is non-cytotoxic, non-sensitizing, a non-irritant, not acutely systemically toxic, and non-pyrogenic.

8.8 Software and Cybersecurity

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. Cybersecurity documentation is provided in support of the subject device per FDA guidance document, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 2023*.

9.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.