October 1, 2021

Jiangsu Jiyuan Medical Technology Co., Ltd.
℅ Yuling Chen
Consultant
Microkn Business Consulting (Shanghai) Co., Ltd
Room 1219, Block A, No 3699, Gonghexin Road, Jingan District
Shanghai, 200435
China

Re: K210270
Trade/Device Name: Medical Endoscope Image Processing System
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: August 25, 2021
Received: August 25, 2021

Dear Yuling Chen:

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)*
K210270

Device Name
Medical Endoscope Image Processing System

Indications for Use *(Describe)*
The Medical Endoscope Image Processing System is intended to be used for viewing of the adult 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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510K summary

According to the requirements Per 21 CFR §807.92, the following information is provided sufficient detail to understand the basis for a determination of substantial equivalence.

Company:	Jiangsu Jiyuan Medical Technology Co., Ltd.
Address:	No. 48 CECEP (Taizhou) Environmental Protection Technology Industry Park, No.59 Meilan Road, Hailing District, Taizhou, Jiangsu, China Postcode: 225300
Date Prepared	September 30, 2021
Device Name:	Medical Endoscope Image Processing System
Common Name	Medical Endoscope Image Processing System
Regulation Number	21 CFR 884.1690
Regulation Name	Hysteroscope and accessories
Product Code	HIH
Product Code Name	Hysteroscope (And Accessories)
Regulatory Class	II

Predicate Device:	Hysteroscope System (K181545) manufactured by Shanghai AnQing Medical Instrument CO., Ltd. The predicate device has not been subject to any design related recalls.
Legal Manufacturer:	Jiangsu Jiyuan Medical Technology Co., Ltd. No. 48 CECEP (Taizhou) Environmental Protection Technology Industry Park, No.59 Meilan Road, Hailing District, Taizhou ,Jiangsu,ChinaPostcode: 225300
Consultant	
Company	Microkn Business Consulting (Shanghai) Co., Ltd.
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1.Indications for use

The Medical Endoscope Image Processing System is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

2. Description of the Device

The Medical Endoscope 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 tissue. The Disposable Electronic Hysteroscope is sterilized and packaged in a sealed pouch. The Medical Endoscope Image Processor is lightweight and ergonomically designed. It has a connector and locking mechanism for attaching and detaching the Disposable Electronic Hysteroscope. The Medical Endoscope Image Processor contains the remaining electronics, including a power on/off button, a button to adjust the brightness of the LED, a button to allow capture of single images or start/stop a video of the procedure, a video processor, microcontrollers, and firmware.

3. Principles of Operation

The disposable electronic hysteroscope is composed of a handle, an insertion part (including a bending part), an operation part, two connectors and a connecting wire. The disposable electronic hysteroscope is used in conjunction with Jiyuan's medical endoscope image processing system. It is used in the hospital to perform endoscopic surgery in the clinic, to collect and transmit the state of internal operation area to the medical endoscope image processing system, and then display the state of internal operation area on the medical endoscope image processing system. The front end of the hysteroscope is a camera component, and both sides of the camera are LED, and the brightness of the LED can be adjusted through the medical endoscope image processing system. The inner diameter of the instrument channel is 2.0mm, and the biopsy forceps can enter the human body through this channel for sampling and other operations. The head bending angle is 16°. The knob of the operating part can be rotated freely from left to right and 360° from left to right. The water inlet and outlet channels are smooth and well-sealed without water leakage phenomenon. Hence It can meet the needs of uterine dilation and attraction during the endoscopic surgery.

4. Comparison to Predicate Device

The subject and predicate devices have the same intended use – viewing of the cervical canal and uterine cavity for diagnostic and operative procedures;

The subject and predicative device have different technological characteristics as evidenced by the table below, such as energy source, maximum insertion diameter (Tip) , hysteroscope direction of view, and image resolution, etc. The differences in technological characteristics do not raise different questions of safety or effectiveness.

(Please refer to table 005-01 and 005-02 for details).

Table 005-01_Descriptive Comparison				
Serial Number	**ITEM**	**Proposed Device**	**Predicate device Hysteroscope System**	**Discussion**
	Classification Product Code	**HIH**	**HIH**	
	510(k) number	**K210270**	**K181545**	
01	Indications for use	The Medical Endoscope Image Processing System is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.	The Hysteroscope System is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. Note: Hysteroscopes are used as tools to access the uterine cavity and are not, in and of themselves, a method of surgery. Generally recognized indications for diagnostic hysteroscopy include:	SE

Table 005-01_Descriptive Comparison				
Serial Number	**ITEM**	**Proposed Device**	**Predicate device Hysteroscope System**	**Discussion**
	Classification Product Code	**HIH**	**HIH**	
	510(k) number	**K210270**	**K181545**	
			• Amenorrhea • Pelvic pain Generally recognized indications for operative hysteroscopy include: • Directed endometrial biopsy • Polypectomy • Submucous myomectomy • Transection of intrauterine adhesions • Transection of intrauterine septa • Endometrial	

Table 005-01_Descriptive Comparison				
Serial Number	**ITEM**	**Proposed Device**	**Predicate device Hysteroscope System**	**Discussion**
	Classification Product Code	**HIH**	**HIH**	
	510(k) number	**K210270**	**K181545**	
02	System Components	The medical endoscope system is composed of disposable electronic hysteroscope and medical endoscope image processor.	The Hysteroscope System consists of a sterile single-use disposable Rigid Hysteroscope and video processor for clinical image processing.	Similar, with difference in wording, while the actual indications are the same.
03	Optical Image	CMOS	CMOS	SE
04	Image Resolution	160,000 pixels	100,000 pixels	Difference 1
05	Illumination Light Source	LED	LED	SE
06	Inflow and outflow channel for saline instillation	Inflow and outflow channels separately.	Inflow and outflow channels separately .	SE
07	Cannula tip design	The head bending angle is 16±3°.	Angled shaft proximal to tip: Straight: 0º Curved tip:22º	Difference 2

Table 005-01_Descriptive Comparison				
Serial Number	**ITEM**	**Proposed Device**	**Predicate device Hysteroscope System**	**Discussion**
	Classification Product Code	**HIH**	**HIH**	
	510(k) number	**K210270**	**K181545**	
08	Image Transmission	Transmits images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the image showing on a monitor.	Transmits images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the image showing on a monitor.	SE
09	Maximum Insertion Diameter (Tip)	4.8mm	4.0 to 6.4mm depending on model	Difference 3
10	Shaft/Cannula Length	200mm±3%	260mm	Difference 4
11	Energy Source	Hysteroscopy is powered by medical endoscope image processor:5V Image processor for medical endoscope:100-240V ,40VA	Hysteroscope: 5V Video Processor: 5V 2A	Difference 5

Table 005-01_Descriptive Comparison				
Serial Number	**ITEM**	**Proposed Device**	**Predicate device Hysteroscope System**	**Discussion**
	Classification Product Code	**HIH**	**HIH**	
	510(k) number	**K210270**	**K181545**	
12	Sterilization	The Disposable Electronic Hysteroscope is provided sterilized by EO. No re-sterilization is permitted. Video Processor: Non-Sterile	The Rigid Hysteroscope is provided sterilized by EO. No re-sterilization is permitted. Video Processor: Non-Sterile	SE

Table 005-02 Analysis of Differences				
SN	**ITEM**	**Proposed Device**	**Predicate device Hysteroscope System**	**Reason**
Difference 1	Image Resolution	160,000 pixels	100,000 pixels	The higher image resolution allows the operator to see the tissue more clearly.

Table 005-02 Analysis of Differences				
Difference 2	Cannula tip design	The head bending angle is 16±3°.	Angled shaft proximal to tip: Straight: 0º Curved tip:22º	The slightly smaller angle allows for more flexible use of the hysteroscope.
Difference 3	Maximum Insertion Diameter (Tip)	4.8mm	4.0 to 6.4mm depending on model	Submission product contains 2mm instrument working channel.
Difference 4	Shaft/Cannula Length	200mm±3%	260mm	According to the design of the human uterine cavity and vagina depth, 200mm is enough to meet the inspection and surgical operation; too long may cause improper operation to damage the endometrium of the uterine cavity

Table 005-02 Analysis of Differences				
Difference 5	Energy Source	Hysteroscopy is powered by medical endoscope image processor:5V Image processor for medical endoscope: 100-240V ,40VA	Hysteroscope: 5V Video Processor: 5V 2A	Submission product has passed the IEC 60601-1-2:2014，IEC 60601-1:2005+A1:2012 and IEC 60601-2-18:2009,the same as predicate device.So this difference doesn't raise any safety or effectiveness issue.

5. Summary of Non-Clinical Performance Testing

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

5.1 Software

The software embedded in the Medical Endoscope Image Processing System is a moderate level of concern. The software was comprehensively verified and validated in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical devices.

Software development activities included establishing detailed software requirements, detailed design specification, trace the requirements to software verification and validation testing, source code reviews, unit testing, system testing, and defect tracking to ensure the software conforms to the user needs and intended purposes.

5.2 Biocompatibility testing

Biocompatibility testing for the Disposable Electronic Hysteroscope was performed in accordance with the recommendations of ISO 10993-1, Biological Evaluation of Medical Device - Part 1: Evaluation and Testing. The results of these tests are listed in the table below:

Biocompatibility testing summary	
Test	**Testing Summary**
Cytotoxicity	Pass-Non-cytotoxic
Irritation test	Pass-Non-irritation
Sensitization test	Pass-Non-sensitization
Intracutaneous reactivity test	Pass-Non-intracutaneous reactivity
Systemic Toxicity test (Acute)	Pass-Non-toxic
Pyrogen test	Pass-Non-pyrogenicity

5.3 Safety, Electrical Safety, and Electromagnetic Compatibility (EMC)

Safety, Electrical Safety, and EMC testing were conducted on the Medical Endoscope Image Processing System in accordance with IEC 60601-1 for Basic Safety and Essential Performance, IEC 60601-1-2 for Electromagnetic Disturbances, IEC 60601-2-18 for Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

5.4 Sterility

The Disposable Electronic Hysteroscope is provided sterile. The method employed for the sterilization of the Disposable Electronic Hysteroscope is Ethylene oxide sterilization according to the EN 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. All sterilized Reservoir Patches met the standard of EN ISO 11135:2014 to assurance a sterility assurance level (SAL) of 10^{-6}.

5.5 Cleaning and Disinfection

The Medical Endoscope Image Processor is reusable. The device needs to be cleaned and disinfected before and after each use. The 75% medical alcohol should be used to thoroughly disinfect the surface of the machine head, including corners and connectors.

5.6 PACKAGING/SHELF LIFE

Simulated shipping testing, accelerated aging testing, and sterility package validation were carried out to support the shelf life of the Disposable Electronic Hysteroscope. Testing results demonstrated that the life of the Disposable Electronic Hysteroscope is 3 years.

The packaging of the Disposable Electronic Hysteroscope was validated for a shelf life of 36 months according to the requirements of ISO 11607-1:2009, ASTM F1980-16, ASTM F88/F88M-15, ASTM D 3078-02, ASTM F1929-15 and ASTM F1140/F1140M-13.

Shipping distribution tests for the Disposable Electronic Hysteroscope and Medical Endoscope Image Processor were conducted per ASTM D4169-16 to simulate shipping hazard exposure climate conditioning, vehicle stacking, vehicle vibration, loose load vibration, and drop to conduct relative tests. Results demonstrated that package integrity for the Disposable Electronic Hysteroscope and Medical Endoscope Image Processor were maintained following shipping and distribution.

The shelf life of the medical endoscope image processor is the same as its service life, which is 5 years. The main components that affect the service life of the product are switching power supply and PCB, and the main factors that determine the service life of these components are temperature and humidity. The service life of the medical endoscope image processor

was evaluated using an accelerated constant stress life test at elevated temperature and humidity. During testing, normal operation and static storage are performed alternately. Accelerated life test results and risk analysis support that the product can be used for up to 5 years.

6. Summary

Based on the verification and validation as documented in the non-clinical performance testing, the Medical Endoscope Image Processing System was found to have a safety and effectiveness profile that is similar to the predicate device.

7. Conclusion

The subject and predicate devices have the same intended use. Although there are differences in the technological characteristics of the subject and predicate devices, these differences do not raise different questions of safety or effectiveness. Results of performance testing have demonstrated that the subject device is as safe and effective as the the predicate device.