April 9, 2018

Chongqing Jinshan Science & Technology (Group) Co., Ltd.
Qing Xu
Regulatory Manager
Yubei District No. 18 Ningshang Avenue Jinshan
International Industrial City
Chongqing, 400000
China

Re: K172151
Trade/Device Name: Hysteroscopy System
Regulation Number: 21 CFR§ 884.5070
Regulation Name: Vacuum Abortion System
Regulatory Class: II
Product Code: HGH
Dated: March 6, 2018
Received: March 9, 2018

Dear Qing Xu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172151

Device Name
Hysteroscopy System

Indications for Use *(Describe)*
The Hysteroscopy System is indicated for rapid transcervical aspiration of the uterine cavity during the first trimester of pregnancy. It has an additional feature of visualization.

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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Chongqing Jinshan Science & Technology (Group) Co., Ltd.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**
   04/06/2018

2. **Submitter's Information [21 CFR 807.92(a)(1)]**

Company Name:	Chongqing Jinshan Science & Technology (Group) Co., Ltd.
Company Address:	Yubei District No.18 Ningshang Avenue Jinshan International Industrial City, Chongqing,
Contact Person:	Qing Xu
Phone:	023 - 86098111
Fax:	023 - 86098777
Email:	xuq@jinshangroup.net

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	Hysteroscopy System
Common Name:	Vacuum Abortion System
Product Code:	HGH (cannula, suction, uterine)
Regulation Name:	Vacuum Abortion System
Regulation Number:	21CFR 884.5070
Device Class:	II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

The identification of predicates within this submission is as follow:

Manufacturer:	DONGGUAN MICROVIEW MEDICAL TECHNOLOGY CO., LTD.
Trade Name:	Disposable Endoscopic Cannula
FDA 510(k) #:	K140213

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

5. **Description of the Device [21 CFR 807.92(a)(4)]**

The Hysteroscopy System is designed to visualize the uterus and to facilitate physicians in the procedure of vacuum aspiration of the uterine cavity during the first trimester of pregnancy. Components of the Hysteroscopy System include an EO-sterilized single-use cannula and reusable image processing unit. The Hysteroscopy System is available in five sizes that differ in length and width.

Each cannula includes an internal channel to draw vacuum or negative pressure up to 500 mmHg. The optical system, which includes a CMOS image sensor, lens, and 40 mW LED, is located at the distal end of the cannula. A lens cover shields the electronics from bodily fluids. The Hysteroscopy System has two connectors: one is an electrical/data connection and the second connection is for vacuum. The cannula is not indicated for use with any other accessories. The patient-contacting materials are medical grade stainless steel, polycarbonate, medical glue, and medical nylon.

6. Indications for Use [21 CFR 807.92(a)(5)]

The Hysteroscopy System is indicated for rapid transcervical aspiration of the uterine cavity during the first trimester of pregnancy. It has an additional feature of visualization.

The subject and predicate device have the same intended use.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

The Hysteroscopy System has different technological characteristics in comparison to the named predicate, primarily with respect to the optics and image quality, internal device construction, and materials used for device construction. However, these differences in technological characteristics do not raise different questions of safety and effectiveness.

8. Summary of Performance Data [21 CFR 807.92(b)]

The following performance data were provided to support substantial equivalence:

- Ethylene oxide sterilization validation per ISO 11135-1:2007
- Shelf Life including packaging integrity following simulated shipping and mechanical performance testing as described below
- Biocompatibility including cytotoxicity per ISO 10993-5:2009, sensitization per ISO 10993-10:2010 and irritation per ISO 10993-10:2010
- Software documentation per the FDA Software Guidance
- Electromagnetic compatibility testing per IEC 60601-1-2:2014

- Electrical safety testing per AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 and IEC 60601-2-18: 2009
- Mechanical performance testing including dimensional analysis, tensile strength, vacuum integrity, vacuum performance, and leak testing
- Image quality testing including field of view, direction of view, illumination, and resolution per the ISO 8600 series of standards

The protocol and results of all performance testing were acceptable.

9. Conclusion [21 CFR 807.92(b)(3)]

The performance data demonstrate that the Hysteroscopy System is substantially equivalent to the predicate device.