DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 25, 2015

Dongguan Microview Medical Technology Co.
% Long Yang
Company Representative
Shenzhen Hlongmed Biotech Co., Ltd
15-08 East Block, Yihai Plaza, Chuangye Road North
Nanshan District, Shenzhen
P.R. China, 518054

Re: K140213
Trade/Device Name: Disposable Endoscopic Cannula
Regulation Number: 21 CFR 884.5070
Regulation Name: Vacuum abortion system
Regulatory Class: II
Product Code: HGH
Dated: February 10, 2015
Received: February 20, 2015

Dear Long Yang,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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 on last page.

510(k) Number *(if known)*

K140213

Device Name

Disposable Endoscopic Cannula, model: RL1205, RL1206, RL1207, RL1208, RL1209

Indications for Use *(Describe)*

The Disposable Endoscopic Cannula 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K140213
Date of Preparation: March 24, 2015

1. Submitter information

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2. Contact person

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3. Device Information

Trade Name: Disposable Endoscopic Cannula
Model: RL1205, RL1206, RL1207, RL1208, RL1209
Common Name: Uterine Cannulae
Regulatory Class: II

Classification Name	Product Codes	Regulation Number
Vacuum Abortion System	HGH	21 CFR 884.5070

4. Predicative Device

Item	Predicate Device
Device Name	Rigid Uterine Cannulae
Common Name	Uterine Cannulae
Manufacturer	Doranne Frano
Classification regulation	21CFR 884.5070
Classification and	Class II
Product code	HGH
510(k) number	K093508

5. Indications for Use

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

6. Device Description

The Disposable Endoscopic Cannula is a sterile, single patient use device composed of transparent cover, suction orifice, dual-function cannula, handle, suction port, connection port, and data cable. The patient contacting components of this device are transparent cover, suction orifice and dual function cannula that are manufactured with polycarbonate.

The transparent cover contains a LED light source and CMOS camera at the distal end for visualization of the cervical canal and uterine cavity. This device has two channels, one for transcervical aspiration of the uterine cavity and the other for transmitting the image signal through a cable connected to the Endoscopic Workstation. The images captured by the camera are transmitted to the endoscopic workstation through the cable for display. When the embryo tissues are located, the operator sucks out the embryo tissues through the suction orifice connected to a vacuum source.

The Disposable Endoscopic Cannula is provided with five sizes based on outer cannula diameter: 5mm (RL1205 model), 6mm (RL1206 model), 7mm (RL1207 model), 8mm (RL1208 model), and 9mm (RL1209 model) (outer diameter). All models have a length of 170mm.

7. Summary of non-clinical data

Biocompatibility: The biocompatibility data from cytotoxicity, irritation and

sensitization testing demonstrated that the Disposable Endoscopic Cannula is in compliance with requirements in ISO 10993-5 and ISO 10993-10.

Electrical Safety and Electromagnetic Compatibility: Electrical Safety and Electromagnetic Compatibility data demonstrates that the device is in compliance with IEC 60601-1, IEC 60601-2-18 and IEC 60601-1-2.

Bench testing: Optical performance testing has demonstrated that this device is in compliance with ISO 8600-1, ISO 8600-3, ISO 8600-4, and ISO 8600-5. In addition, this device has been evaluated for tensile strength, vacuum integrity, and vacuum performance

8. Comparison to Predicate Device

Parameter	Subject device (K140213)	Predicate device (K093508)
Device name	Disposable Endoscopic Cannula	Rigid Uterine Cannulae
Intended use	Same as the predicate, with additional feature of visualization	For rapid transcervical aspiration of the uterine cavity during the first trimester of pregnancy
Design	Curved in shape two channels One channel for aspiration The other channel for data transmission via cable	Straight or curved in shape One channel for aspiration
Working length	Maximal 170 mm	Maximal 190 mm
Outer diameter	5-9 mm	6-12 mm
Material	Polycarbonate	Plastic (Styrenic copolymer resin)
Built in camera	Yes	No
Light source	Yes	No

Substantial equivalent discussion:

- The Disposable Endoscopic Cannula and the predicate device have the same intended use – uterine aspiration.

- The Disposable Endoscopic Cannula and the predicate device have the same fundamental technological designs (shape, suction channel, etc.) and comparable dimensions.

- The Disposable Endoscopic Cannula is different from the predicate device in that it has a light source, raising a safety concern. The difference does not raise new

types question because light source is common in other uterine devices (e.g., hysteroscopes). The difference can be assessed by accepted electrical safety, EMC, thermal safety and photoviological safety testing methods. The electrical safety, EMC, thermal safety and photobiological safety testing showed that the Disposable Endoscopic Cannula is safe.

- Unlike the predicate device, the Disposable Endoscopic Cannula has a camera that can capture the image of uterine cavity. The imaging function of this device is supported by optical performance data including image resolution, distortion, depth of view, field of view, direction of view, etc.

- The Disposable Endoscopic Cannula uses different material, raising safety concerns. There is no new type of question, because biocompatibility is a common question for patient-contacting medical devices. The biocompatibility testing showed that the Disposable Endoscopic Cannula is safe.

- To ensure mechanical performance, the Disposable Endoscopic Cannula was evaluated for tensile strength, suction integrity, and suction performance. The results demonstrated that the Disposable Endoscopic Cannula is safe and effective.

In conclusion, the Disposable Endoscopic Cannula is substantially equivalent to the predicate device in terms of safety and effectiveness.