November 18, 2019

Reed Medical (Zhejiang) Co., Ltd.
% Daniel Qiu
Project Manager
Shanghai Qisheng Business Consulting Co., Ltd.
Room 1301, Bld 46, Jing Gu Zhong Rd. No. 58, Min Hang
District, Shanghai, CN
Shanghai, Shanghai 200240
CHINA

Re: K190797
Trade/Device Name: Reedgyn disposable hysteroscope (Model RH-2S-01 and Model RH-2D-01)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: II
Product Code: HIH
Dated: October 15, 2019
Received: October 15, 2019

Dear Daniel Qiu:

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,

for Sharon Andrews
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190797

Device Name
Reedgyn disposable hysteroscope (Model RH-2S-01 and Model RH-2D-01)

Indications for Use *(Describe)*
The Reedgyn disposable hysteroscope RH-2D-01 is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures in an outpatient or office setting. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

The Reedgyn disposable hysteroscope RH-2S-01 is 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 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

I. Submitter's information

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Date prepared: November 17, 2019

II.Device

Device trade name: Reedgyn disposable hysteroscope (Model RH-2S-01 and Model RH-2D-01)
Classification name: Hysteroscope and Accessories
Regulation class: II
Regulation number: 21CFR 884.1690
Panel: Obstetrics/Gynecology
Product code: HIH

III.Predicative device

K132384, U-scope 8000 System With Hsc+emb Cannula.

IV.Device description

The Reedgyn disposable hysteroscopes, which include models RH-2S-01 and RH-2D-01, are used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures (both RH-2S-01 and RH-2D-01) and to obtain an endometrial tissue sample (biopsy) in an outpatient or office setting (RH-2S-01 only).

RH-2S-01 and RH-2D-01 are similar in design. The only difference between RH-2S-01 and RH-2D-01 is: RH-2S-01 is intended for performing diagnostic procedures and obtaining an endometrial tissue sample (biopsy), while the RH-2D-01 is intended for performing diagnostic procedures only. Key performance specifications and device characteristics are listed in the table below.

The Reedgyn disposable hysteroscopes consist of a lightweight handle, a cannula integrated with a camera and a light source at the distal end to illuminate the area for visualizing images. The distal end of the cannula is equipped with a camera module including a camera and LED lightling. LED irradiates the surface of the object, and the reflected light enters the image processor through a lens and converts it into electrical signals, and then converted into a digital image signal , which is transmitted to the digital signal processing chip. After chip processing, the signal is transmitted to PC through USB interface.

The Reedgyn disposable hysteroscopes should be operated together with Reedgyn hysteroscope imaging software which was installed to a Microsoft Windows PC station. (Note: the Windows PC station is not included in the product configuration.)

Parameter	**Specification**
Cannula length	270mm
Outer diameter	RH-2D-01: 4.9mm RH-2S-01: 7.8mm
Inner diameter	RH-2D-01: -Fluid channel (In & out): 1.3mm RH-2S-01: -Fluid channel (In & out): 1.2mm -Accessory channel: 2mm
Handle width	28 mm
Handle height	25 mm
Direction of view	20° ± 5°
Field of view	100° ± 5°
Number of pixels	1280 x 720
Depth of field	5-50mm
Light Source	LED

The Reedgyn disposable hysteroscope is provided sterilea sealed pouch. It is for single use.

The Reedgyn disposable hysteroscope operates on 5V DC working voltage.

The general type of materials in the device are PEBAX® thermoplastic elastomers

(Cannula) and polycarbonate (Connector). The The Reedgyn disposable hysteroscope components are part of an external communicating device (Tissue/bone/dentin) in direct tissue contact for a duration ≤24 hours. . The biocompatibility of the Reedgyn disposable hysteroscope was established via testing of the final, finished product (see performance testing section below).

The Reedgyn disposable hysteroscopes are intended to be used in hospitals and physician offices.

V.Indication for use

The Reedgyn disposable hysteroscope RH-2D-01 is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures in an outpatient or office setting. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

The Reedgyn disposable hysteroscope RH-2S-01 is 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 bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

The indications for use of Reedgyn disposable hysteroscopes are similar to that of predicate device. The indications for the RH-2D-01 falls within the indications of the predicate, but does not include biopsy.

VI. Comparison of Technological Characteristics

Attribute	Subject device	Predicative device U-Scope 8000 Hsc+emb Cannula
510(k) number	K190797	K132384
Indication for use	The Reedgyn disposable hysteroscope RH-2D-01 is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures in an outpatient or office setting. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage,	The predicative device is 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

Attribute	Subject device	Predicative device U-Scope 8000 Hsc+emb Cannula
	evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain. The Reedgyn disposable hysteroscope RH-2S-01 is 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 bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.	(biopsy) in an outpatient or office setting. The sample is used for cytologic and histologic diagnosis. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.
Procedures	Uterine diagnostic for RH-2D-01, Uterine diagnostic and endometrial biopsy for RH-2S-01	Uterine diagnostic and endometrial biopsy
Environment of use	Hospitals and physician offices	Hospitals and physician offices
Intended user	Physicians with adequate training in hysteroscopy	For use only by physicians with adequate training in hysteroscopy.
Device features: -Components	• CMOS camera • semi-rigid cannula • USB interface electronics • USB cable	• Image-capturing hand tower; • attachable cannula with outflow and inflow ports in which suction can be created and with a curette near its tip.
-Cannula outer diameter	RH-2S-01: 7.8 mm RH-2D-01: 4.9 mm	4.3mm
-Accessory channel	RH-2D-01: N/A RH-2S-01: 2mm	N/A
-Cannula	Flexible	Flexible

Attribute	Subject device	Predicative device U-Scope 8000 Hsc+emb Cannula
-Cannula length	270mm	276mm
-Illumination light source	LEDs	LEDs
-Hysteroscope field of view	100 ° ±5°	100° ±5°
-Hysteroscope direction of view	20° ±5°	20° ±3°
-Depth of field	5-50mm	4-45mm
-Imaging transmission	Over USB interface to a viewing station	Image transmitted from a video camera to a video monitor on the handle
-Number of pixels	1280 x 720	400*400
-Optical image	Digital CMOS	Digital CMOS technology
Disposable/Reusable	Disposable/ only single usage	Reusable handle and a sterile disposable diagnostic cannula
Battery charge indication	n/a – no battery	Charge indication as an icon on the LCD monitor
Battery power	n/a – no battery	3.7V
Adjust brightness of LEDs	n/a – brightness is managed by camera exposure and gain	Adjust by depressing a button on the hand tower
Capture still or video images during procedure	Controlled by keyboard and foot switch interfaces	Capture still or video during procedure by depressing a camera button on the hand tower
Enter patient ID information prior to procedure	User interface allows physician to add patient information	User interface on monitor allows physician to add patient information.
Duration of use	≤2 hours	≤24 hours
Sterilization	Entire product is sterile following exposure to ethylene oxide (EO).	Hand tower is not sterile. The U-scope 8000 HSC+EMB cannula is sterile following exposure to ethylene oxide(EO).
Frequency of use	Disposable for a single usage	Hand tower is reusable. The

Attribute	Subject device	Predicative device U-Scope 8000 Hsc+emb Cannula
		U-scope 8000 HSC+EMB cannula is single patient use.
Tissue contact material	Compliant with ISO 10993	Compliant with ISO 10993

The subjective device and predicative device have the same intended use. The subject and predicative device have different technological characteristics as evidenced by the table above. The differences in technological characteristics do not raise different questions of safety or effectiveness.

VII.Summary of non-clinical testing

The following performance data were provided to verify that the subject device met all design specifications. The results demonstrated that the subject device is as safe and effective as the predicate device..

- Risk Analysis developed in accordance with ISO 14971:2007.
- Electrical Safety Testing in accordance with IEC 60601-1:2005 (3rd Edition).
  - The subject device was demonstrated to meet applicable sections of the standard.
- Electromagnetic Compatibility Testing in accordance with lEC 60601-1-2:2014.
  - The subject device was demonstrated to be electromagnetically compatible in its intended environment of use.
- Medical electrical equipment - Part 2-18: "Particular requirements for the basic safety and essential performance of endoscopic equipment" (IEC60601-2-18:2009).
  - The subject device met the requirements of the standard.
- Biocompatibility Tests in accordance with lS0 10993, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010),irritation (ISO 10993-10:2010) and acute systemic toxicity (ISO 10993-11:2017).
  - The subject device was demonstrated to be non-cytotoxic, non-irritating, non-sensitizing, and not acutely toxic.
- Software Validation - Software Life Cycle Processes in accordance with lEC 62304:2015, and Guidance for Industry and FDA staff-Guidance for the content of premarket submissions for software contained in medical devices.Document issued on:May 11,2005.
  - The software of the subject device was demonstrated to function as intended per specification.
- Endoscopes-medical endoscopes and endotherapy devices-Part 1:General requirements-(ISO 8600-1:2015).
  - The subject device was demonstrated to meet the requirements of the

standard.

- Optics and optical instruments — Medical endoscopes and endoscopic accessories —Part 3: Determination of field of view and direction of view of endoscopes with optics AMENDMENT 1.(ISO 8600-3:2003).
  - The subject device was demonstrated to meet the requirements of the standard.
- Endoscopes — Medical endoscopes and endotherapy devices —Part 4: Determination of maximum width of insertion portion.(ISO 8600-4:2014).
  - The subject device was demonstrated to meet the requirements of the standard.
- Optics and photonics — Medical endoscopes and endotherapy devices — Part 5:Determination of optical resolution of rigid endoscopes with optics.(ISO 8600-5:2005).
  - The subject device was demonstrated to meet the requirements of the standard.

Due to its labeling as sterile, the Reedgyn disposable hysteroscope underwent sterilization validation and shelf life testing to confirm the label shelf life and was found in compliance with the following:

- Sterilization of health-care products - Ethylene oxide Requirements for the development, validation and routine control of a sterilization process for medical devices. (ISO 11135:2014).
- Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems. (ISO 11607-1:2006).
- Standard guide for accelerated aging of sterile barrier systems for medical devices (ASTM F1980-16).
- Sterilization of medical devices-Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process(ISO 11737-2:2009).
- Standard test method for determination of leaks in flexible packaging by bubble emission(ASTM D3078-02(2013)).
- Standard test method for detecting seal leaks in porous medical packaging by dye penetration(ASTM F1929-15).
- Sterilization-sterile supply –Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized(DIN 58953-6:2016).
- Standard test method for seal strength of flexible barrier materials(ASTM F88/F88M-15).

Results from testing demonstrate assurancethe device is sterile and remains sterile throughout the proposed shelf life.

VIII.Conclusion

The Reedgyn disposable hysteroscopes have similar indications to that of the predicate. The RH-2D-01 indications fall within those of the predicate, and the difference does not alter the intended use. The technological differences between Reedgyn disposable hysteroscopes and the predicate device do not raise different questions of safety and effectiveness. Performance testing as described above has demonstrated that the subject device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.