June 26, 2018

Beijing HangTian KaDi Technology R&D Institute
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K172846
Trade/Device Name: HK-WQ-I and HK-WQ-II Uterine Manipulators
HK-ZQ-I and HK-ZQ-II Uterine Manipulators
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: May 11, 2018
Received: May 24, 2018

Dear Diana Hong:

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 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,

Michael T. Bailey -S

for
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)* K172846

K172846

Device Name HK-WQ-I and HK-WQ-II Uterine Manipulators
HK-ZQ-I and HK-ZQ-II Uterine Manipulators

Indications for Use *(Describe)*

The HK-WQ-I and HK-WQ-II are indicated for manipulation of the uterus, and injection of fluids during laparoscopic gynecologic procedures such as laparoscopic supracervical hysterectomy, minilap tubal ligation, laparoscopic tubal occlusion or diagnostic laparoscopy.

The HK-ZQ-I and HK-ZQ-II are intended for use in laparoscopic procedures where it is desirable to delineate the vaginal fornices and the surgeon intends to remove or access intraperitonial tissue through the vagina by use of a colpotomy or culdotomy incision; such as laparoscopically assisted vaginal hysterectomies, total laparoscopic hysterectomies, while maintaining pneumoperitoneum by sealing the vagina while a colpotomy is performed.

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 – K172846

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

Date of Preparation: June 25, 2018

Sponsor Identification:

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Submission Correspondent:

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Subject Device Information:

Trade Name:	HK-WQ-I and HK-WQ-II Uterine Manipulators HK-ZQ-I and HK-ZQ-II Uterine Manipulators
Common Name:	Uterine Manipulator
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Regulation Number:	21 CFR 884.4530
Class:	II
Product Code:	LKF (cannula, manipulator/injector, uterine)
Review Panel:	Obstetrics and Gynecology

Indications for Use Statement:

The HK-WQ-I and HK-WQ-II are indicated for manipulation of the uterus and injection of fluids during laparoscopic gynecologic procedures such as laparoscopic supracervical hysterectomy, minilap tubal ligation, laparoscopic tubal occlusion or diagnostic laparoscopy.

The HK-ZQ-I and HK-ZQ-II are intended for use in laparoscopic procedures where it is desirable to delineate the vaginal fornices and the surgeon intends to remove or access intraperitonial tissue through the vagina by use of a colpotomy or culdotomy incision; such as laparoscopically assisted vaginal hysterectomies, total laparoscopic hysterectomies, while maintaining pneumoperitoneum by sealing the vagina while a colpotomy is performed.

Device Description:

There are four versions of the subject device. HK-WQ-I and HK-WQ-II have a curved central guide rod, while the HK-ZQ-I and HK-ZQ-II have a central guide rod which can be rotated (or "flexed") up or down using a dial on the handle.

Each device is a sterile, disposable, single-patient use device which consists of a manipulator shaft with an inflatable intrauterine balloon at the proximal end. The intrauterine balloon is inflated by liquid via a standard syringe injected through the check valve. The internal injection tip of the manipulator shaft is open to allow direct intrauterine introduction of medicine liquid via the injector port. The device also incorporates a vaginal sealing balloon which is inflated by liquid via a standard syringe injected through the check valve to seal the vagina and maintain pneumoperitoneum. The location and orientation of the uterus can be adjusted by the handle.

Each device version can be used with a cervical cup. During use, the open-end of the cup rests on the cervix. There are two versions of the cup- a ceramic version and a polyphenylene sulfite version. For both materials, the cup is available in four different sizes - 30mm, 35mm, 40mm and 46mm.

Predicate Device Information:

Predicate Device 1 for the HK-WQ Curved version:
510(k) Number: K093556
Trade Name: Vcare Dx
Sponsor: Conmed Corporation

Predicate Device 2 for the HK-ZQ Flexed version:
510(k) Number: K131781
Trade Name: Clearview Total
Sponsor: Clinical Innovations

The predicate devices have not been subject to a design related recall.

Substantially Equivalent (SE) Comparison:

Table 1 Comparison of Technology Characteristics for HK-WQ

Item	Proposed Device	Predicate Device 1 K093556
Product Code	LKF	LKF
Regulation Number	21 CFR 884.4530	21 CFR 884.4530
Indications for Use	The HK-WQ-I and HK-WQ-II are indicated for manipulation of the uterus and injection of fluids during laparoscopic gynecologic procedures such as laparoscopic supracervical hysterectomy, minilap tubal ligation, laparoscopic tubal occlusion or diagnostic laparoscopy.	VCARE Dx uterine manipulator/injector cannula is indicated for manipulation of the uterus, and injection of fluids during laparoscopic gynecologic procedures such as laparoscopic supracervical hysterectomy, minilap tubal ligation, laparoscopic tubal occlusion or diagnostic laparoscopy.
Curved Shaft	Yes	Yes
Liquid introduction	Yes	Yes

Balloon inflation	Yes	Yes
Cervical cup	Yes	Yes
Prevents loss of pneumoperitoneum	Yes	Yes

Table 2 Comparison of Technology Characteristics for HK-ZQ

Item	Proposed Device	Predicate Device 2 K131718
Product Code	LKF	LKF
Regulation Number	21 CFR 884.4530	21 CFR 884.4530
Indications for Use	The HK-ZQ-I and HK-ZQ-II are intended for use in laparoscopic procedures where it is desirable to delineate the vaginal fornices and the surgeon intends to remove or access intraperitonial tissue through the vagina by use of a colpotomy or culdotomy incision; such as laparoscopically assisted vaginal hysterectomies, total laparoscopic hysterectomies, while maintaining pneumoperitoneum by sealing the vagina while a colpotomy is performed.	The ClearView Uterine Manipulator Device with ColpCup and Occluder is intended for use in laparoscopic procedures where it is desirable to delineate the vaginal fornices and the surgeon intends to remove or access intraperitonial tissue through the vagina by use of a colpotomy or culdotomy incision; such as laparoscopically assisted vaginal hysterectomies, total laparoscopic hysterectomies, while maintaining pneumoperitoneum by sealing the vagina while a colpotomy is performed.
Bending Angle	180 degree total range of motion	210 degree total range of motion
Liquid introduction	Yes	Yes
Balloon inflation	Yes	Yes
Cervical cup	Yes	Yes
Prevents loss of pneumoperitoneum	Yes	Yes

Each version of the subject device has the same intended use as its respective predicate. Each subject device also has different technological characteristics (design, material composition) compared to its respective predicate device; however, the differences in technological characteristics do not raise different questions of safety or effectiveness.

Summary of Non-Clinical Performance Tests:

The following non-clinical tests were conducted on the subject devices:

- Biocompatibility include cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010), irritation (ISO 10993-10:2010), acute systemic toxicity (ISO 10993-11:2006), and pyrogenicity (USP <151> and ISO 10993-11:2006)
- Mechanical performance testing

- For the HK-WQ-I, HK-WQ-II, HK-ZQ-I, and HK-ZQ-II, the following tests were performed:
  - dimensional specifications
  - intrauterine balloon tensile and burst strength tests
  - uterus shaft deflection force test
  - movement force test
  - intrauterine balloon inflation cycling
- For the versions which include the vaginal balloon (i.e., HK-WQ-II and HK-ZQ-II) the following additional tests were performed:
  - vaginal sealing balloon maximum inflation volume test
  - vaginal sealing balloon tensile strength under maximum inflation volume
  - vaginal sealing balloon sealing characteristics
  - vaginal sealing balloon air leakage test
- For the cervical cup, the following tests were performed
  - dimensional specifications
  - structural strength
  - tension resistance
  - locking force
  - movement force

- Sterilization validation per ISO 11135:2017
- Shelf life testing including package integrity and mechanical performance testing

Conclusion:

The results of performance testing demonstrate the subject devices are substantially equivalent to their respective predicate devices.