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

August 19, 2015

Gynetech PTY. LTD.
% Christopher Sloan
Principal Consultant
Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852

Re: K150519
Trade/Device Name: ManipulatOR PRO, ManipulatOR
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: July 23, 2015
Received: July 24, 2015

Dear Christopher Sloan,

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,

Joyce M. Whang -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)*
K150519

Device Name
ManipulatOR and ManipulatOR PRO

Indications for Use *(Describe)*
The ManipulatOR is indicated for manipulation of the uterus during laparoscopic procedures including laparoscopic assisted vaginal hysterectomy (LAVH), laparoscopic tubal occlusion, and diagnostic laparoscopy. The ManipulatOR, when used together with the McCartney Tube, is indicated for manipulation of the uterus during laparoscopic procedures requiring maintenance of pneumoperitoneum, such as total laparoscopic hysterectomy (TLH).

The ManipulatOR PRO is indicated for manipulation of the uterus during laparoscopic procedures such as laparoscopic assisted vaginal hysterectomy (LAVH), total laparoscopic hysterectomy (TLH), laparoscopic tubal occlusion and diagnostic laparoscopy. The ManipulatOR PRO maintains pneumoperitoneum by sealing the vagina once 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 FOR K150519

ManipulatOR and ManipulatOR PRO

510(k) Owner

Brett Telford
Managing Director
Gynetech Pty Ltd
122-124 Balmain Street
Richmond VIC 3121, Australia
Phone: +61 3 9413 5588
Fax: +61 3 9413 5556
Email: btelford@gynetech.com.au

Official Correspondent

Christopher M. Sloan
Principal Consultant
Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852
Phone: (301) 272-3114
Facsimile: (301) 272-0004
Email: chris.sloan@quintiles.com

Date Prepared: 18 August 2015

Device Tradename: ManipulatOR and ManipulatOR PRO

Device Common or Usual Name: ManipulatOR and ManipulatOR PRO (Cannula, Manipulator / Injector, Uterine)

Classification Name and Regulation Number, Class, Panel, and Product Code

Classification Name and Regulation Number	Class	Product Code (Device Name)	Panel
None	Unclassified	LKF (Cannula, Manipulator / Injector, Uterine)	Obstetrics/Gynecology

Predicate Device: ManipulatOR and ManipulatOR PRO (K142164)

Device Description: The ManipulatOR and ManipulatOR PRO are sterile, single-use uterine manipulators indicated for uterine manipulation and preventing loss of pneumoperitoneum during laparoscopic gynecology procedures. The ManipulatOR and ManipulatOR PRO are silicone insulated and anatomically designed stainless steel manipulators with a silicone intrauterine balloon at one end and an external handle at the other end. The balloon is inflated with air using a 20cc syringe that is supplied with the device.

The ManipulatOR and ManipulatOR PRO are designed to improve physician visibility of the uterus and cervix during various medical examinations and procedures. Like many uterine elevators currently in the market place, the ManipulatOR and ManipulatOR PRO are designed for use in surgical procedures requiring cervical uterine motions with elevation and retraction of the vaginal fornices. The ManipulatOR and ManipulatOR PRO can help to create the tension on the tissue to assist in ligament dissection. In the most commonly used procedure, the total laparoscopic hysterectomy, the uterine elevator must expose the fornix and seal the vagina following removal of the uterus.

Intended Use / Indications for Use: The ManipulatOR is indicated for manipulation of the uterus during laparoscopic procedures including laparoscopic assisted vaginal hysterectomy (LAVH), laparoscopic tubal occlusion, and diagnostic laparoscopy. The ManipulatOR, when used together with the McCartney Tube, is indicated for manipulation of the uterus during laparoscopic procedures requiring maintenance of pneumoperitoneum, such as total laparoscopic hysterectomy (TLH).

The ManipulatOR PRO is indicated for manipulation of the uterus during laparoscopic procedures such as laparoscopic assisted vaginal hysterectomy (LAVH), total laparoscopic hysterectomy (TLH), laparoscopic tubal occlusion and diagnostic laparoscopy. The

ManipulatOR PRO maintains pneumoperitoneum by sealing the vagina once colpotomy is performed.

Technological Characteristics: The following characteristics are shared by both device systems (Original Gynetech ManipulatOR and the modified Gynetech ManipulatOR):

- Are provided sterile by means of EO sterilization and are single use
- Are designed for use in the uterus and vagina
- Have a plastic handle that remains outside the patient for gripping and positioning by the surgeon
- Incorporate an anatomically curved stainless steel shaft
- Use an inflatable intrauterine balloon at the end of the shaft
- Packaged in single peel Tyvek pouch
- Use identical materials for the shaft; balloon
- Use biocompatible materials

The following characteristics are shared by both device systems (Original Gynetech ManipulatOR PRO and the modified Gynetech ManipulatOR PRO):

- Are provided sterile by means of EO sterilization and are single use
- Are designed for use in the uterus and vagina
- Have a plastic handle that remains outside the patient for gripping and positioning by the surgeon
- Incorporate an anatomically curved stainless steel shaft
- Incorporate a cervical cup and a vaginal cup
- Use an inflatable intrauterine balloon at the end of the shaft
- Are available with a variety of sizes of cervical cup
- Packaged in single peel Tyvek pouch
- Use identical materials for the shaft; vaginal cup; cervical cup; valve
- Use biocompatible materials

The following characteristics differ between the Original Gynetech ManipulatOR and the modified Gynetech ManipulatOR:

- The original ManipulatOR did not incorporate colorants within the silicone shaft overmould and balloon material, whereas, the modified ManipulatOR incorporates a blue colorant

The following characteristics differ between the Original Gynetech ManipulatOR PRO and the modified Gynetech ManipulatOR PRO:

- The original ManipulatOR PRO did not incorporate colorants within the silicone material, vaginal cup or cervical cup, whereas, the modified ManipulatOR PRO incorporates a blue colorant within the silicone shaft overmould and balloon, a blue colorant in the vaginal cup and a green colorant in the various sizes of cervical cups

The technological similarities between the Gynetech Original Gynetech ManipulatOR / ManipulatOR PRO and the modified Gynetech ManipulatOR / ManipulatOR PRO devices show that the devices are substantially equivalent in intended use and operation, design, anatomical site of usage, most materials, sterilization, and biocompatibility.

Performance: The ManipulatOR and ManipulatOR PRO were subjected to safety and performance testing by the manufacturer for the initial 510(k) review. The materials used in the original and modified ManipulatOR and ManipulatOR PRO devices are well-characterized, commonly-used materials that have passed all biocompatibility testing, including cytotoxicity, vaginal irritation, guinea pig maximization sensitization, and an assessment of the toxicological risks of colorants. The performance testing undertaken for the initial 510(k) review demonstrated the functionality and safety of the device for its intended use.

Conclusion

The information and data provided in this 510(k) establish that the modified ManipulatOR and ManipulatOR PRO are substantially equivalent to the aforementioned predicate devices.