



Food and Drug Administration
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October 27, 2016

Surgitools Pty Ltd.
% Elizabeth Pugh
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Austin, Texas 78701

Re: K161065
Trade/Device Name: ColpoWave™ Colpotomizer and CerviGrip™
Uterine Manipulator
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: Class II
Product Code: HEW
Dated: September 28, 2016
Received: September 28, 2016

Dear Elizabeth Pugh:

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>.

For Division

Sincerely yours,

Douglas Silverstein -S

2016.10.27 15:26:25 -04'00'

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

Indications for Use

510(k) Number (if known)

K161065

Device Name

ColpoWave™ Colpotomizer and CerviGrip™ Uterine Manipulator

Indications for Use (Describe)

The ColpoWave Colpotomizer and CerviGrip Uterine Manipulator is indicated for use by a surgeon in laparoscopic procedures where uterine manipulation and visualization of the position of the vaginal fornices for colpotomy incisions is required, and for maintaining pneumoperitoneum during vaginal vault closure.

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

K161065

1. Submission Sponsor

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3. Date Prepared

October 14, 2016

4. Device Identification

Trade/Proprietary Name:	ColpoWave™ Colpotomizer and CerviGrip™ Uterine Manipulator
Common/Usual Name:	Uterine Manipulator and Colpotomizer
Classification Name:	Culdoscope and accessories
Regulation Number:	884.1640
Product Code:	HEW, Culdoscope and accessories LKF, Cannula, manipulator/injector, uterine
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

K110819, Singh Colpotomizer System, Surgitools Pty Ltd.

6. Device Description

The Surgitools Pty Ltd. ColpoWave Colpotomizer and CerviGrip Uterine Manipulator consists of the ColpoWave™ Colpotomizer, CerviGrip™ Uterine Manipulator, and the ColpoWave™ Balloon

accessory. All parts are made without natural latex rubber and supplied sterile to be disposed of after use.

The single-use CerviGrip™ Uterine Manipulator is designed with an integrated cervical screw, a sliding uterine tip, tail screw that can lock the uterine tip in place, and a screw to hold the colpotomizer in place. The CerviGrip™ Uterine Manipulator is manufactured with ABS polymer and 304 Stainless Steel.

The ColpoWave™ Colpotomizer is non-fenestrated and has incorporated two different sizes due to the double-ended colpotomizer design (30mm or 40mm diameter). Cup shape with one partial circumferential raised lip at each end and a second partial raised circumferential lip 20mm from each end providing the surgeon with a known distance to help gauge pelvic distances during dissection. The ColpoWave™ Colpotomizer is manufactured with green ABS polymer to provide better visualization (greater contrast than white against tissue).

The ColpoWave™ Balloon is an optional accessory, which is inflated to fit various vaginas.

7. Indications for Use Statement

The ColpoWave Colpotomizer and CerviGrip Uterine Manipulator is indicated for use by a surgeon in laparoscopic procedures where uterine manipulation and visualization of the position of the vaginal fornices for colpotomy incisions is required, and for maintaining pneumoperitoneum during vaginal vault closure.

8. Predicate Comparison

The following table compares the Surgitools ColpoWave Colpotomizer and CerviGrip Uterine Manipulator to the predicate device with respect to indications for use, technological characteristics, and materials:

Trade Name	Singh Colpotomizer System K110819 (Surgitools Pty Ltd.)	ColpoWave Colpotomizer and CerviGrip Uterine Manipulator K161065 (Surgitools Pty Ltd.)
Indications for use	The Singh Colpotomizer System is indicated for use by a surgeon in laparoscopic procedures requiring uterine manipulation and the visualization of the position of the vaginal fornices for colpotomy incisions into the vaginal vault. The surgeon makes the colpotomy incisions to access or remove intraperitoneal tissue from the pelvic cavity.	The ColpoWave Colpotomizer and CerviGrip Uterine Manipulator is indicated for use by a surgeon in laparoscopic procedures where uterine manipulation and visualization of the position of the vaginal fornices for colpotomy incisions is required, and for maintaining pneumoperitoneum during vaginal vault closure.

System Components	<ul style="list-style-type: none"> • Uterine manipulator with cervical screw attachment; • Sliding uterine tip (inner rod); • Sliding and rotating funnels (available in two sizes) with a lip acting as a colpotomizer; • O-ring and screw to hold the funnel in place; and • Vaginal occluder (plastic vaginal plug) 	<ul style="list-style-type: none"> • Uterine manipulator with cervical screw attachment • Sliding uterine tip • Sliding and rotating colpotomizer (incorporating two sizes) • ColpoLock and screw to hold the colpotomizer in place; • Pneumatic plug (PneumoBloc); and • Vaginal occluder (ColpoWave Balloon)
Uterine Tips	Single length inner rod	Single length inner rod
Vaginal Plug	OD 43mm Length 50mm	ColpoWave Balloon is inflated to fit various vaginas
Design Colpotomizer	<ul style="list-style-type: none"> • Two colpotomizers of different sizes. 35mm and 40mm • Cup shape with partial circumferential raised lip at its end. • White. • Non-fenestrated. 	<ul style="list-style-type: none"> • One colpotomizer incorporating two different sizes. One side diameter 30mm and one of diameter 40mm • Cup shape with one partial circumferential raised lip at each end and a second partial raised circumferential lip 20mm from each end. • Green. • Non-fenestrated.
Uterine manipulator	<ul style="list-style-type: none"> • Uterine manipulator with cervical screw attachment; • Sliding uterine tip (inner rod); • Tail screw with hydrotubation port; and • O-ring and screw to hold the funnel in place 	<ul style="list-style-type: none"> • Uterine manipulator with integrated cervical screw and hydrotubation port; • Sliding uterine tip; • Tail screw that can lock the uterine tip in place; and • ColpoLock and screw to hold colpotomizer in place.
Materials	Stainless steel and polymer	Stainless steel and polymer
Single use or reusable	Reusable	Single use
Biocompatible materials	Yes	Yes

The Surgitools ColpoWave Colpotomizer and CerviGrip Uterine Manipulator has the same intended use but different technological characteristics compared to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the ColpoWave Colpotomizer and CerviGrip Uterine Manipulator and in showing substantial equivalence to the predicate device, Surgitools Pty Ltd. completed a number of tests and validations. The ColpoWave Colpotomizer and CerviGrip Uterine Manipulator meets all the requirements for overall design, sterilization, and biocompatibility confirming that the design output meets the design inputs and specifications for the device.

The ColpoWave Colpotomizer and CerviGrip Uterine Manipulator passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Performance Testing

The device successfully passed bench testing to evaluate mechanical and functional properties to ensure the device is robust to withstand forces that exceed the expected forces during use, including tensile tests, manipulation, and balloon strength and stability.

- Biocompatibility testing per ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-11

The subject device is an external communicating device that contacts tissue for less than 24 hours. Cytotoxicity, Intracutaneous Reactivity, Sensitization, and Acute Systemic Toxicity Testing were performed. All tests were conducted on the finished device after manufacturing, packaging, and sterilization had been completed to reflect the actual state of the device when exposed to the patient. All patient-contacting device components passed biocompatibility testing required by ISO 10993-1 and FDA General Program Memorandum G95-1.

- Sterilization Validation

The sterility of the Surgitools Uterine Manipulator and Colpotomizer system is assured by using a validated sterilization method qualified in accordance with ISO 11135-1. The validation results met the acceptance criteria defined in the standard and demonstrates the ability of the process to deliver SAL of 10^{-6} . Examination of the EtO residuals has been conducted in accordance with ISO 10993-7, which has validated a minimum release period of 7 days.

- Shelf Life Testing

After the sterilization cycle was complete, the products were accelerated aged and tested to demonstrate no degradation in strength or functionality over the anticipated shelf life period of three (3) years.

10. Clinical Performance Data

There was no human clinical testing required to support the substantial equivalence of the subject device.

11. Conclusion

Based on the comparison and analysis above, the Surgitools ColpoWave Colpotomizer and CerviGrip Uterine Manipulator is substantially equivalent to the referenced predicate device.