K110819

OCT - 5 2011

Preparation Date:	September 29, 2011
Submission Correspondent:	Emergo Group, Inc. www.emergogroup.com/
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Contact:	Caroline Tontini
Submission Sponsor:	Surgitools Pty Ltd. 231 Timberlane Drive Woodvale, W.Australia, 6026 Australia Phone: +618 93093222 Fax: +618 93093736
Device Trade Name:	Singh Colpotomizer System
Device Common Name:	Uterine Manipulator and Vaginal Delineator
Classification Name:	Culdoscope (and Accessories) 884.1640, HEW
Device Class:	2

Legally Marketed Devices to which Substantial Equivalence is Claimed:
The Koh Colpotomizer System
510(k) Number: K954311
CooperSurgical, Inc

Intended Use:
The Singh Colpotomizer System 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. The surgeon makes the colpotomy incisions to access or remove intraperitoneal tissue.

Device Description:
The Singh Colpotomizer System is comprised of a reusable uterine manipulator with cervical screw attachment, a reusable sliding uterine tip (inner rod), reusable sliding and rotating funnels with a lip acting as a colpotomizer, an O ring and screw to hold the funnel in place, and a vaginal plug. The funnels are available in two sizes: 35 and 40mm.

In Laparoscopic Hysterectomy, the Uterine Cannula is inserted into the Uterus. The Vaginal Funnel slides onto the Uterine Cannula and is rotated manually during the operation to lift the Vaginal Wall for identification and incision during Laparoscopic Hysterectomy. This identifies the uterine arteries and ureters during this procedure.

Stainless steel and medical grade plastics are used in the manufacture of the subject device.

Comparison to the Predicate Device:

The Singh Colpotomizer System has the same intended use as the Koh Colpotomizer System. The two devices use slightly different design features to achieve the same results; i.e. anterversion and retroversion of uterus, providing a landmark for vaginal vault incision, and maintenance of pneumoperitoneum during colpotomy and vaginal vault closure.

Both devices have 35mm and 40mm colpotomizers.

Both devices are provided non sterile and contain reusable components. All components of the Singh Colpotomizer System are reusable. The predicate device's silicon parts and balloons must be discarded after one use.

The subject device's inner rod can be retracted to fit variable uterine lengths. The predicate device's uterine tips are not retractable and require a range of uterine tip lengths to fit various uterine lengths.

The Singh Colpotomizer System has a cervical screw on manipulator screws into the endocervical canal and maintains the device in position; while the predicate device features a balloon in the uterine tip which is inflated to hold the device within the uterus.

The Singh funnel is solid and selecting the correct sized non-fenestrated funnel, to provide a snug fit at the vaginal vault to prevent leakage of CO2. The Koh Colpo-Pneumo Occluder balloon is inflated prior to making colpotomy incisions to prevent CO2 leakage.

During uterine morcellation with the subject device, the stainless steel inner rod of the subject device can be retracted so that it does not interfere with the morcellator. Whereas in the predicate device, the plastic uterine tip and balloon cannot be retracted during uterine morcellation.

Similar to the predicate device, the uterus is pulled into the vagina after the colpotomy incisions are completed and acts as a vaginal plug to prevent CO2 leakage while the vaginal vault is sutured. Alternatively, the Singh Colpotomizer utilizes two other methods to maintain pneumoperitoneum if the uterus has been morcellated before delivery.

Summary of Non-Clinical Data Submitted:

The following testing has been performed to support substantial equivalence: Automated and Manual Cleaning Evaluation Validation Reports according to AAMI TIR30:2003, Steam Sterilization Validation Report using the biological indicator (BI) overkill method, ISO Guinea Pig Maximization Sensitization Test, ISO Mucosal (Vaginal) Irritation Test to ISO 10993-10:2002, ISO Acute Systemic Injection Test to ISO 10993-11:2006, MEM Elution Test to ISO 10993-5:2009, and Mediated Pyrogen Test to ISO 10993-11:2006.

Discussion of Clinical Tests Performed:

Clinical performance data from the clinical use of the device in Western Australia since 2002 was presented.

Number of cases:	2148
Number of women included in the study:	2148
Summary of adverse events:	No cases of uterine perforation
	1 case of ureteric injury
	6 cases of bladder injuries
	7 cases of vaginal vault bleeding
	1 case of rectal injury
Number of cases in which pneumoperitoneum was maintained:	2148
Number of cases successfully completed laparoscopically:	2148

Conclusion:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Singh Colpotomizer System and the predicate device do not raise any questions regarding its safety and effectiveness. The Singh Colpotomizer System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Surgitools Pty Ltd.
% Ms. Caroline Tontini
Project Manager
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611 West 5th Street, Third Floor
AUSTIN TX 78701

OCT - 5 2011

Re: K110819
Trade/Device Name: Singh Colpotomizer System
Regulation Number: 21 CFR§ 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: II
Product Code: HEW, LKF
Dated: August 30, 2011
Received: September 1, 2011

Dear Ms. Tontini:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner, M.D., Director (Acting)
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): K110819

Device Name: Singh Colpotomizer System

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110819