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**510(k) Summary  
CooperSurgical  
Koh Colpotomizer System**

**1. Sponsor/Applicant**

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**2. Device Name**

**Proprietary Name:** The Koh Colpotomizer™ System  
**Common/Usual Name:** Uterine Manipulator/Injector and Accessories  
**Classification Name:** Uterine Elevator

**3. Identification of Predicate or Legally Marketed Device(s) to Which Equivalence is Being Claimed**

Lubke Uterine Vacuum Cannula, SEMM Uterine Vacuum Cannula and Milex Inflato Ball

**4. Device Description**

The Koh Colpotomizer™ System consists of two accessory devices: The Koh Cup™ Vaginal Fornices Delineator, and a Colpo-Pneumo Occluder, each of which are specifically designed to attach to and be used with the RUMI uterine manipulator device. The CooperSurgical RUMI device as described in K932115 is intended to be used as a uterine manipulator during pelvic laparoscopic procedures.

The Koh Cup™ Vaginal Fornices Delineator is a plastic cup-shaped device which fits over the distal end of the RUMI disposable tip and firmly attaches to the tip base. When attached to the RUMI, the Koh Cup™ becomes an extension of the uterine manipulator tip and is thus able to articulate up or down as the uterine manipulator is operated in the normal fashion.

With the RUMI and Koh Cup™ properly positioned inside the patient, the outer rim of the Koh Cup™ will surround the cervix and be located in the vaginal fornices. In this position the rim of the Koh Cup™ will extend or "stretch" the vaginal fornices, thus allowing the surgeon an anatomical marker to conveniently locate the position of the fornix when viewed from an intracorporeal position. The kit will include Koh Cups™ in three outer rim diameter sizes: 3.0 cm, 3.5 cm, and 4.5 cm. The surgeon or nurse will make the selection of the appropriate size Koh Cup™ by visual inspection of the cervix at the time of instrument insertion in the patient.

The Pneumo Occluder consists of a condom-like silicone sleeve whose proximal end is folded back and attached to the main shaft of the sleeve in order to form an inflatable cavity (the "occluding balloon"). Attached to the occluding balloon is an inflation catheter that is available to the surgeon outside the patient's body for inflating the occluding balloon during surgery. The occluding balloon should be inflated until it fully contacts the perimeter wall of the vagina. This creates a pressure barrier which prevents the pneumoperitoneum from leaking out of the patient through the vagina once the colpotomy or culdotomy incision is made. This occluding property allows the surgeon to maintain proper pneumoperitoneum pressure and continue the laparoscopic procedure.

In addition to the Koh Cup™ and Colpo-Pneumo Occluder, a 60 cc syringe is included in the proposed kit to be used for filling the occluding balloon with saline. Typically the occluding balloon will require inflation of approximately 100 cc of saline in order to adequately occlude the vagina.

#### **5. Intended use**

The Koh Colpotomizer™ System, comprised of the Koh Cup™ Vaginal Fornices Delineator and Colpo-Pneumo Occluder, are accessories to the RUMI uterine manipulator, K932115.

These accessories are designed to attach to the RUMI uterine manipulator device and are intended to be used by the surgeon as an anatomical marker to locate the position of the vaginal fornices as viewed through uterine tissue from within the abdominal cavity

(intracorporeal), and also to maintain pneumoperitoneum during laparoscopic surgical procedures in which a colpotomy or culdotomy incision is made. The Koh Colpotomizer™ System is used in conjunction with the RUMI uterine manipulator device.

## 6. Technological Characteristics

The Koh Cup™ Vaginal Fornices Delineator device (of the Koh Colpotomizer™ System) and the LUBKE and SEMM uterine cannula predicate device above are identical in technological characteristics in that they all consist of a cup-shaped perimeter that are used with a uterine manipulator. Both the Koh Cup™ and predicate devices consist of a cup-shaped perimeter which fit outside the cervix in the vaginal fornices while the uterine manipulator "finger" goes up through the cervix and inside the uterus. .

The Colpo-Pneumo Occluder device is substantially equivalent to the Milex Inflato Ball and to several common techniques utilized during laparoscopic surgery to prevent loss of pneumoperitoneum. The common technique of inflating a surgical glove with air or to stuff it with surgical gauze, and pushing the glove into the vaginal cavity to occlude the passageway is similar in technological characteristics to the Colpo-Pneumo Occluder. The latex glove is inflated as the Pneumo-Occluder and used as the occluding device. The Pneumo-Occluder is a fixed device that is firmly held in place since it is attached to the uterine manipulator and acts as a vaginal occluding device during surgery. The technological characteristics of the Pneumo-Occluder are also similar to the MILEX Inflato Ball an inflatable pessary device since it is inflated and inserted into the vagina in order to prevent leakage of the pneumoperitoneum during laparoscopic surgery.

## 7. Performance Testing

The Colpo-Pneumo Occluder was subjected to and passed a static burst test which consisted of inflating the balloons with 250 cc of water and left for 12 hours. None of the balloons burst at 10 minutes, 30 minutes, 60 minutes or 12 hour time frames. The criteria for passing the test was maintaining the 250 cc of water for 30 minutes without loss. This is a factor of 2.5 times the inflation generally needed for use in surgery and has been found in practice to be an adequate design margin.