5. Premarket Notification [510(k)] Summary

Date: July 6, 2012

JUL 13 2012

Submitted By:
LSI SOLUTIONS®, Inc.
7796 Victor-Mendon Road
Victor, New York 14564
Phone: (585) 869-6608
Fax: (585) 742-8086

Contact: Jude S. Sauer, M.D., President

Common Name: Uterine Manipulator

Trade Name: LSI SOLUTIONS® ForniSee™ System Uterine Manipulator and Accessories

Classification Name: Culdoscope and Accessories 21 CFR Part 884.1640

Predicate Device: The Koh Colpotomizer™ System (K954311)

Description: LSI SOLUTIONS® ForniSee™ System will provide aid in the tissue manipulation typically encountered in patients requiring a hysterectomy. The ForniSee™ System provides single-patient use FS Devices and its companion reusable FS Sounds; these components are made from common surgical metals and polymers. Sterile disposable, mostly plastic, FS Device surgical hand tools will be offered in three different sizes designated as either FS-30, FS-35 or FS-40, with the number indicating the increasing diameter of the inside of the device's distal cervical cups. The FS Device is designed with an optional integrated vaginal illumination component. FS Sounds are reusable implements, which are essentially customized angled shafts or sounds constructed of cleanable and resterilizable surgical quality metal; the distal ends of these FS Sounds will be offered in four different sizes ranging in length from 6 to 8 to 10 to 12cm. FS Devices fit over FS Sounds to provide an effective means of uterine manipulation during laparoscopic surgery. FS Devices and FS Sounds will be manufactured at our facility in Victor, New York.

Intended Use: The LSI SOLUTIONS® ForniSee™ System is intended for use as a uterine manipulator in laparoscopic hysterectomy surgical procedures to identify the vaginal fornices and manipulate the uterus.

Summary of Technological Characteristics Comparing Study Device to Predicate: Both the selected predicate, Koh Colpotomizer™ System, and the proposed subject, FornisSee™ System, share a common intended use. The predicate and subject devices are intended to be used sterile by a surgeon to assist in intra-operative transvaginal uterine manipulation and to aid in delineating the vaginal fornices region. Both systems assist in the maintenance of pneumoperitoneum after a colpotomy incision is made (Koh: using a balloon; FS: using the elastomeric vaginal occluder). Both systems incorporate durable components that can be reused repeatedly in patients and therefore require means for sufficient cleaning and resterilization. Both systems also incorporate single-patient use components that are provided sterile. Both systems have a plastic handle that remains outside of the patient in the perineal area for gripping and positioning by the operator. Both have a rigid section that passes through the vaginal canal and end in a cup shaped structure intended to engage the patient's cervix from within the vaginal fornices. Both systems provide a range of different size options for cervical engaging cups; cup size selection is typically made when using either system while the patient is in the operating room. Both systems provide several options over a comparable range of lengths for rigid, finger-like, members that enter and engage the uterine cavity; to mechanically anchor this rigid finger into the patient's uterus, the predicate device uses an inflatable balloon and the subject device uses a rotating metal anchor. With either system, rotation and movement of the handle outside of the patient causes reposition of the uterus and enhanced exposure of the area around the colpotomy site. The FS Device incorporates a passageway for the optional transmission of light for vaginal illumination to aid in colpotomy incisions. Both the predicate and subject systems have been demonstrated to be biocompatible and sterilizable. Both systems have been demonstrated in actual patient use to be effective for their intended use to aid in surgery through forniceal exposure and uterine manipulation, while also proving safe by not exposing patients to unacceptable risk.

Performance Testing: A substantial amount of FornisSee™ System performance testing was undertaken throughout the development of this product line. Cadaver research provided highly encouraging results.

The following non-clinical tests were completed:

- ISO Vaginal Irritation and Guinea Pig Maximization tests [ANSI/AAMI BE78:2002/A1:2006 (equivalent to ISO 10993-10:2002/A1:2006)]
- MEM Elution cytotoxicity testing [ISO 10993-5:2009]
- Steam and Sterrad sterilization validation per "Overkill Method" (10^{-6} SAL)
- EO Sterilization validation per "Overkill Method" as recommended in ANSI/AAMI/ISO 11135-1:2007
- Sterilization residuals testing [EO residual testing in accordance to ISO 10993-7:2008]
- Reusable component reprocessing [AAMI TIR No. 30]
- Accelerated aging [ASTM F 1980-07 (2011)]
- Shipping testing [ASTM D4169-09]
- Bench testing including functional, destructive and life testing of FS™ System devices, and thermal testing of the vaginal illumination feature.

Clinical performance testing was achieved through Institutional Review Board approved studies in 50 elective hysterectomy patients at two separate medical centers, each with their own gynecological surgeon Principal Investigator (PI). All hysterectomies were accomplished as pre-planned (38 Total Laparoscopic Hysterectomies and 11 Laparoscopic Supracervical Hysterectomies), except for 1 patient (2% of total) requiring conversion to a Total Abdominal Hysterectomy because of an extremely large uterus. There were no device related Adverse Events. No ureteral injuries occurred. Two patients, one at each site, with significant pre-existing pathologic scarring had inadvertent iatrogenic cystotomies, which were recognized immediately and sutured laparoscopically without any sequelae. Both bladder injuries were considered Not Device Related Adverse Events. The Estimated Blood Loss (EBL) range for this study was 20cc to 300cc with an average of 124cc at one site and 60cc at the other site, with an average of 96cc for both sites combined. Pneumoperitoneum was maintained throughout the procedure with no loss in 47 of 49 patients and a slight loss in 2 patients. Several minor intra-operative observations were noted but deemed by the PIs as expected in their patients or of no significant consequence. For example, one patient received an iatrogenic perforation in her previously therapeutically ablated uterus while dilating with a standard sound at the initiation of the operation. No bleeding or other observances were noted with this perforation. The uterine specimen was removed as planned. No other intra-operative problems or complications were encountered. All patients were reported by study PIs at post-operative follow up examinations to have a normal post-hysterectomy course except one patient who developed coincidental diverticulitis, requiring hospital admission and antibiotic therapy. Several other observations were made regarding study patients' post-operative recovery. For example, one patient complained of modest post-op transient vaginal bleeding; no bleeding or pathology was noted upon exam. Another patient required antibiotic therapy for a urinary tract infection. Another patient developed acute cholecystitis after her hysterectomy; this development was not considered attributable to her study procedure or an abnormal post-hysterectomy event by that site's PI. The use of these study devices reported by both PIs were proven to be highly effective especially in patients with challenging anatomy.

Conclusion:

Both the predicate and the subject systems offer many similar features and functions from comparable structural components. The bench top and clinical results affirm the effectiveness, safety and durability of the ForniSee™ System product. We believe that the predicate and the subject devices have been demonstrated to be substantially equivalent.

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

Jude S. Sauer, M.D.
President and CEO
LSI SOLUTIONS®, Inc.
7796 Victor-Mendon Road
VICTOR NY 14564

JUL 13 2012

Re: K111014
Trade/Device Name: LSI SOLUTIONS® ForniSee™ System Uterine Manipulator and Accessories
Regulation Number: 21 CFR§ 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: II
Product Code: HEW, LKF
Dated: July 6, 2012
Received: July 9, 2012

Dear Dr. Sauer:

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,

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): K111014

Device Name: LSI SOLUTIONS® ForniSee™ System Uterine Manipulator and Accessories

Indications For Use:

The LSI Solutions® ForniSee™ System is intended for use as a uterine manipulator in laparoscopic hysterectomy surgical procedures to identify the vaginal fornices and manipulate the uterus.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K111014