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## 5. 510(k) SUMMARY

**1. Submitter:**

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Telephone: 508.875.1343, ext. 112

Contact: John J. Vozella, VP Clinical & Regulatory Affairs
Date Prepared: December 17, 2010

**2. Device:**

Trade Name: SurgiSure™ Tissue Removal System
Common Name: Endoscope and accessories
Classification Name: Endoscope and accessories
Class: II

**3. Predicate Device:**

MyoSure™ Hysteroscopic Tissue Removal System (K091100 & K100559)
VersaCut™ Tissue Morcellator System (K050639)

**4. Device Description:**

The SurgiSure™ Hysteroscopic Tissue Removal System consists of the following procedural components:

- SurgiSure™ Tissue Removal Device
- SurgiSure™ Control Unit
- SurgiSure™ Foot Pedal

The SurgiSure™ Control Unit contains an electric motor and firmware motor controller that drives the SurgiSure Tissue Removal Device. The Control Unit motor is activated and deactivated by the SurgiSure Foot Pedal. The SurgiSure Tissue Removal Device is a tissue morcellator that is connected to the Control Unit via a flexible drive cable. The SurgiSure Tissue Removal Device features a rotating/reciprocating (2mm OD) cutter blade encased in a (3 mm OD) outer tube. The device's cutter blade is controlled by a drive system that enables simultaneous rotation and reciprocation of the cutter. The cutter is also connected to a vacuum source which aspirates resected tissue through a side-facing cutting window in the device's outer tube. Distension fluid and resected tissue are transported from the SurgiSure Tissue Removal Device to a tissue trap and vacuum canister via a tube protruding from the proximal end of the Tissue Removal Device. The SurgiSure Tissue Removal System is compatible with commercially available fluid management systems and may be used with endoscopes that have a straight ≥3 mm working channel.

5. **Intended Use:**
The SurgiSure™ Tissue Removal System is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.

6. **Comparison of Characteristics:**
The principles of operation and primary functional specifications of the SurgiSure™ Tissue Removal System are identical to those of the predicate MyoSure™ Hysteroscopic Tissue Removal System, K091100 & K100559 and similar to those of the predicate VersaCut™ Morcellator System, K050639. Each device employs a sterile, straight surgical morcellator for tissue removal. A foot pedal controls activation and deactivation of the motor which powers the morcellator in all three devices. All three devices access the target treatment site through a sheath or endoscope with a straight working channel and all devices simultaneously morcellate and aspirate tissue from the operative site.

The SurgiSure™ morcellator is identical to the predicate MyoSure™ morcellator in that it consists of a single use, disposable rotating and reciprocating inner tube or cutter that is totally contained within a stationary outer tube and has a vacuum tube fitting at its proximal end to enable aspiration of resected tissue. The SurgiSure inner tube or cutter rotates and reciprocates at a fixed rate that is identical to the predicate MyoSure device. The SurgiSure cutter blade tip design is identical to that of the predicate MyoSure device and the outer tube design of both devices incorporates a side-facing "cutting window" through which targeted tissue is pulled, cut, and moved back through the inner tube to a collection canister.

The SurgiSure™ Tissue Removal System's intended use is identical to that of the predicate VersaCut™ Morcellator System and similar to that of the predicate MyoSure Hysteroscopic Tissue Removal System.

The SurgiSure™ Tissue Removal System is different from the predicate MyoSure™ Hysteroscopic Tissue Removal System and VersaCut Morcellator System as follows:

- The SurgiSure Control Unit's electric motor, motor control firmware and electronic circuitry components are identical to those found in the predicate MyoSure device, but are different from those found in the VersaCut device.
- The SurgiSure Tissue Removal Device is dimensionally identical to the predicate MyoSure device except that it is longer than the MyoSure device to facilitate access of the cutter blade to target tissue. The SurgiSure Tissue Removal Device is smaller in diameter and lighter than the predicate VersaCut Morcellator System.

- Instructions for use for the SurgiSure™ Tissue Removal System have been changed from the predicate MyoSure™ Hysteroscopic Tissue Removal System instructions for use to reflect the SurgiSure device's intended use.
- Because the SurgiSure Tissue Removal Device is smaller in diameter than the predicate VersaCut Morcellator System, it's tissue cutting rate is similar to but slightly slower than the VersaCut Morcellator System.

**7. Performance Testing:**

The SurgiSure™ Tissue Removal System meets electrical safety and EMC standards. Patient contact materials in the SurgiSure device meet the biocompatibility requirements of ISO 10993-1 Biological Evaluation of Medical Devices. In addition, in-vitro testing demonstrated that the SurgiSure™ Tissue Removal System performs equivalent to the predicate VersaCut™ device.

**8. Conclusion:**

Based on the intended use, descriptive information and performance evaluation provided in this submission, the SurgiSure™ Tissue Removal System has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate MyoSure™ Hysteroscopic Tissue Removal System and VersaCut™ Morcellator System.

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

Interlace Medical, Inc.
% Mr. John J. Vozella
Vice President, Clinical & Regulatory Affairs
135 Newbury Street
Framingham, Massachusetts 01701

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Re: K103741
Trade/Device Name: SurgiSure™ Tissue Removal System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 22, 2010
Received: December 23, 2010

Dear Mr. Vozella:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103741

Device Name: SurgiSure™ Tissue Removal System

Indications For Use:

The SurgiSure™ Tissue Removal System is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103741