5. 510(k) SUMMARY

OCT 15 2010

1. Submitter:

Interlace Medical Inc.
135 Newbury St
Framingham, MA 01701
Telephone: 508.875.1343, ext. 112

Contact: John J. Vozella, VP Clinical & Regulatory Affairs
Date Prepared: September 14, 2010

2. Device:

Trade Name: MyoSure™ Single Use Seals
Common Name: Hysteroscope and accessories
Classification Name: Hysteroscope and accessories
Class: II

3. Predicate Device:

MyoSure™ Rod Lens Hysteroscope and Accessories (K091465)

4. Device Description:

The MyoSure™ Rod Lens Hysteroscope incorporates a 3 mm ID working channel and a proximal seal. Additionally, the MyoSure™ Rod Lens Hysteroscope utilizes a removable 3.0 mm OD outflow channel which also includes a seal to prevent distension fluid leakage from its proximal end. The seal also provides an insertion pathway for handheld instruments or cautery probes.

MyoSure™ Rod Lens Scope Seals are comprised of white-tinted silicone.

5. Intended Use:

MyoSure™ Single Use Seals are a component / accessory to the MyoSure™ Rod Lens Hysteroscope and are used to prevent distension fluid leakage from the proximal ends of the MyoSure™ Rod Lens Hysteroscope and removable outflow channel.

6. **Comparison of Characteristics:**
The design, principles of operation, primary functional specifications and materials of composition of the modified MyoSure™ Single Use Seals are equivalent to those of the predicate scope seals described in the MyoSure™ Rod Lens Hysteroscope (K091465) submission in that:

- all seals are fabricated from silicone,
- all seals are dimensionally identical,
- all seals are required to be sterile prior to being placed in the MyoSure™ Rod Lens Hysteroscope and outflow channel,

The modified MyoSure™ Single Use Seals' intended use is identical to that of the predicate scope seals (K091465).

7. **Performance Testing:**
The modified MyoSure™ Single Use Seals meet the biocompatibility requirements of ISO 10993-1 Biological Evaluation of Medical Devices as well as bench test performance requirements established by Interlace Medical, Inc.

8. **Conclusion:**
Based on the intended use, descriptive information and performance evaluation provided in this submission, the modified MyoSure™ Single Use Seals have been shown to be equivalent in technology, method of operation, functional performance and intended use to the previously referenced predicate seals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. John Vozella
V.P. Clinical and Regulatory Affairs
Interlace Medical, Inc.
135 Newbury Street
FRAMINGHAM MA 01701

OCT 15 2010

Re: K102686
Trade Name: MyoSURE™ Single Use Seals
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: September 14, 2010
Received: September 17, 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,

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

4. INDICATIONS FOR USE STATEMENT

OCT 15 2010

510(k) Number (if known): K102686

Device Name: MyoSure™ Single Use Seals

Indications For Use:

MyoSure™ Single Use Seals are a component / accessory to the MyoSURE™ Rod Lens Hysteroscope and are used to prevent distension fluid leakage from the proximal ends of the MyoSure™ Rod Lens Hysteroscope and removable outflow channel.

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102686