MAR 2 3 2012

5. 510(k) SUMMARY

1. Submitter:

Hologic, Inc.
250 Campus Dr.
Marlborough, MA 01752
Telephone: 508.263.8857

Contact: Sarah Fairfield, Sr. Regulatory Affairs Specialist

2. Device:

Trade Name: MyoSure™ Hysteroscopic Tissue Removal System
Common Name: Hysteroscope and accessories
Classification Name: Hysteroscope and accessories
Class: II

3. Predicate Device:

MyoSure™ Hysteroscopic Tissue Removal System (K100559)

4. Device Description:

The modified Myosure Hysteroscopic Tissue Removal System consists of the following procedural components which are identical to those found in the predicate Myosure System:

- Myosure Control Unit
- Myosure Tissue Removal Device
- Myosure Foot Pedal

The Myosure Control Unit contains an electric motor and software controller that drives the Myosure Tissue Removal Device. The Control Unit motor is activated and deactivated by the Myosure Foot Pedal. The Myosure Tissue Removal Device is a tissue morcellator that is connected to the Control Unit via a flexible drive cable. The morcellator'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 Myosure Tissue Removal Device to a tissue trap and vacuum canister via a tube protruding from the proximal end of the Tissue Removal Device. The Myosure Hysteroscopic Tissue Removal System is compatible with commercially available fluid management systems and may be used with hysteroscopes that have a straight 3 mm working channel.

5. Intended Use:

The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

6. Comparison of Characteristics:

The modified Myosure Hysteroscopic Tissue Removal System's intended use and indicated use are identical to that of the predicate Myosure Hysteroscopic Tissue Removal System, K100559.

The principles of operation and primary functional specifications of the modified Myosure Hysteroscopic Tissue Removal System are identical to those of the predicate Myosure Hysteroscopic Tissue Removal System.

The modified Myosure Hysteroscopic Tissue Removal System is different from the predicate Myosure Hysteroscopic Tissue Removal System as follows:

- The motor within the control unit now rotates bidirectionally

7. Performance Testing:

Performance verification testing of the modified Myosure Hysteroscopic Tissue Removal System was completed using the same methodology as was used in support of the predicate Myosure System 510(k) submission (K100559). Testing evaluated cutting functionality and heat generation over the test interval for the modified Myosure System. Test results for the predicate and modified Myosure Hysteroscopic Tissue Removal Systems were then compared. Results from this testing demonstrated that:

- the modified Myosure System's fibroid cutting performance is equivalent to that of the predicate device
- cutter durability over time is equivalent for the modified and predicate Myosure Systems
- heat generation over time is equivalent for the modified and predicate Myosure Systems

Verification/validation testing of the modified Myosure System was completed and confirmed that the modified Myosure System meets the same functional and performance specifications as the predicate Myosure System.

8. Conclusion:

Based on the intended use, descriptive information and performance evaluation provided in this submission, the modified MyoSure Hysteroscopic 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.

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

MAR 2 3 2012

Ms. Sarah Fairfield
Senior Regulatory Affairs Specialist
Hologic, Inc.
250 Campus Drive
MARLBOROUGH MA 01752

Re: K120593
Trade/Device Name: Myosure Hysteroscopic Tissue Removal System
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: February 27, 2012
Received: February 29, 2012

Dear Ms. Fairfield:

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

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K120593

Device Name: Myosure Hysteroscopic Tissue Removal System

Indications For Use:

The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120593