DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 13, 2015

Hologic, Inc
Catherine Eaton
Regulatory Affairs Specialist
250 Campus Drive
Marlborough, MA 01752

Re: K152723
Trade/Device Name: Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH
Dated: October 29, 2015
Received: October 30, 2015

Dear Catherine Eaton,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152723

Device Name
Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices

Indications for Use *(Describe)*
The MyoSure Tissue Removal System and Tissue Removal Devices are intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as:

Submucous myomas
Endometrial Polyps
Retained products of conception

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Hologic, Inc.
Special 510(k) Submission
November 12th, 2015

510(k) SUMMARY

Date: November 12th, 2015

510(k) Submitter:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
Attn: Catherine Eaton
P: 508.263.8604
F: 508.263.2403

Establishment Registration Number: 1222780

Trade Name: Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices

Common/Usual Name: Hysteroscope and Accessories, 21.CFR.Reg 884.1690

Product Code: HIH

Classification: Class II

Panel: Obstetrics/Gynecology

Predicate Device:

Trade name: Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices
Submitter / 510(k) Holder: Hologic, Inc.
510(k) **#:** K142029 Classification code: HIH and Regulation: 21.CFR.884.1690

DEVICE DESCRIPTION

The Myosure Hysteroscopic Tissue Removal System consists of the following procedural components which are identical to those found in the sponsor's previously cleared device:

- Tissue Removal Drive System
- Tissue Removal Device (TRD)
- Foot Pedal

The Myosure Hysteroscopic Tissue Removal System uses mechanical resection to remove endometrial polyps, submucous myomas, and retained products of conception hysteroscopically from the uterus. Mechanical resection allows the surgeon to have precise control of the locations and extent of tissue resected by drawing the targeted tissue into the cutting window under suction while the inner blade cuts the tissue.

Indications for Use:

The Myosure Hysteroscopic Tissue Removal System and Tissue Removal Devices are intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as:

Submucous myomas
Endometrial Polyps
Retained products of conception

Comparison of Characteristics:

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 primary change to the Myosure Hysteroscopic Tissue Removal System is the modification of the Myosure Tissue Removal Device (TRD) used with the system (to be named Myosure Reach TRD). The MyoSure Reach TRD will be part of the family of the MyoSure TRDs utilized with the Myosure Hysteroscopic Tissue Removal System.

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

- Cutting window has been shifted farther down the distal end of the morcellator.
- The tolerance within the firmware has been tightened to coincide with the dimensional change made by shifting the window farther down the distal tip
- The helix within the TRD has been modified to improve manufacturability and optimize the bidirectional movement of the motor.

The differences between the subject device and predicate do not raise any new types of safety and effectiveness questions. The difference in cutting window placement and helix design were evaluated by performance bench testing

The fundamental scientific technology of the proposed device has not changed relative to the predicate device (K142029):

- Has the same mechanism of action and mode of operation,
- Is manufactured using the same materials,
- Is packaged and sterilized using the same process,
- Has the same shelf life.

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. The Myosure Tissue Removal Devices and modified Control Units were used to cut beef tongue tissue; each device was tested for a 30 minute duration test interval. 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 tissue 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 and meets IEC 60601-1 thermal safety requirements.

The modified device software/firmware was assessed per the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. 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.

Conclusion:

The proposed Myosure Tissue Removal System met all acceptance criteria for design verification and validation, as specified by applicable standards, guidance, test protocols and/or customer inputs. The proposed Myosure Tissue Removal System is substantially equivalent to the legally marketed predicate device (Hologic's Myosure Tissue Removal Device System and Tissue Removal Devices).