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

September 20, 2017

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

Re: K172566
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: II
Product Code: HIH
Dated: August 28, 2017
Received: August 30, 2017

Dear Catherine Sanford:

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 (DICE) 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 (DICE) 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172566

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

Indications for Use *(Describe)*
The Myosure Hysteroscopic Tissue Removal System and Myosure 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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510(k) SUMMARY

Date: September 18th, 2017

510(k) Submitter:

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

Establishment Registration Number: 1222780

Subject Device:

Trade Name: Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices
Common/Usual Name: Hysteroscope and Accessories
Product Code: HIH
Classification Name: Hysteroscope and Accessories, 21.CFR.Reg 884.1690
Classification: Class II
Panel: Obstetrics/Gynecology

Predicate Device:

Trade Name: Myosure Tissue Removal Device System and Myosure Tissue Removal Devices
Submitter / 510(k) Holder: Hologic, Inc.
510(k) #: K152723 Classification code: HIH, Hysteroscope and Accessories, and Regulation: 21.CFR.884.1690
This predicate has not been subject to a design-related recall.

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
- 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. There have been no major changes in design or materials in the subject Myosure System or its associated tissue removal devices since their market clearance.

Indications for Use:
The Myosure Hysteroscopic Tissue Removal System and Myosure 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 modified Myosure Hysteroscopic Tissue Removal System is different from the predicate Myosure Hysteroscopic Tissue Removal System as follows:

- The process of manufacturing the outer sheath of the device handpiece has been brought in-house to Hologic Inc.
- The cutting window of the outer tube is being cut into the tube using a laser rather than the previously used electronic discharge machining (EDM)
- The process used to clean the outer tube following cutting of the window has been modified to include alkaline cleaning, nitric acid electropolish, and passivation in accordance with ASTM-A967/A967M -13 *Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts*.

The fundamental scientific technology of the proposed device has not changed relative to the predicate device (K152723):

- Has the same Indications for Use,
- Has the same mechanism of action and mode of operation,
- Is manufactured using the same raw materials,

- Is packaged and sterilized using the same process,
- Has the same shelf life.

Biocompatibility Testing:

Biocompatibility testing of the modified MyoSure Hysteroscopic Tissue Removal Device outer tubes was conducted to demonstrate that the modified cleaning process does not negatively impact the biocompatibility of the device. Testing was completed using the same methodology as was used in support of the predicate MyoSure Hysteroscopic Tissue Removal System 510(k) submission and in accordance with both AAMI/ISO 10993-1:2009/(R) 2013 *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process* and the FDA Guidance for Industry and Food and Drug Administration Staff titled *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and dated June 16, 2016. Cytotoxicity, systemic toxicity, intracutaneous reactivity, and maximization sensitization studies were completed in accordance with the standards ISO 10993-5:2009, ISO 10993-11:2006, and ISO 10993-10:2010 respectively. Results from this testing demonstrated that the modified cleaning process does not negatively impact the biocompatibility of the device for the specified use conditions and is therefore substantially equivalent to that of the predicate device.

Performance Testing:

Performance verification testing of the modified Myosure Hysteroscopic Tissue Removal System was not required because there is no modification to the design of the outer tube of the device. An engineering assessment of the cutting method determined there was no impact to the cutting performance of the device as a result of the change in manufacturing process.

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).