August 23, 2018

Hologic, Inc
Rachelle Fitzgerald
Senior Regulatory Affairs Specialist
250 Campus Drive
Marlborough, MA 01752

Re: K181974
Trade/Device Name: MyoSure XL Tissue Removal Device for Fluent
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: Class II
Product Code: HIH
Dated: July 23, 2018
Received: July 24, 2018

Dear Rachelle Fitzgerald:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for
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)*
K181974

Device Name
MyoSure XL Tissue Removal Device for Fluent

Indications for Use *(Describe)*
The MyoSure XL Tissue Removal Device for Fluent in 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) SUMMARY

**Date:** August 22, 2018, 2018

**510(k) Submitter:**

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
Attn: Rachelle D. Fitzgerald
P: 508.263.8631
F: 877.793.6434

**Establishment Registration Number:** 1222780

**Trade Name:** MyoSure XL Tissue Removal Device for Fluent

**Common/Usual Name:** Hysteroscope and Accessories

**Regulation Name:** Hysteroscope and Accessories

**Regulation Number:** 21CFR 884.1690

**Product Code**: HIH, Hysteroscope and Accessories

**Classification:** Class II

## PREDICATE DEVICES

**Tradename:** Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices
**Submitter/510(k) Holder:** Hologic, Inc.
**510(k) #:** K172566
**Product Code**: HIH
**Regulation**: 21CFR 884.1690

The Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices has not been subject to a design-related recall.

## DEVICE DESCRIPTION

The MyoSure XL Tissue Removal Device for Fluent is a sterile, single-use device that is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: Submucous myomas, Endometrial Polyps, Retained products of conception. The MyoSure XL Tissue Removal Device for Fluent is designed to be used with a hysteroscope and to connect to the Fluent Fluid Management System.

The MyoSure XL Tissue Removal Device for Fluent uses mechanical resection which allows the

surgeon to have precise control over 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 MyoSure Tissue Removal Devices since their market clearance.

**INDICATIONS FOR USE:**
The MyoSure XL Tissue Removal Device for Fluent is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as:
Submucous myomas
Endometrial Polyps
Retained products of conception.

The MyoSure XL Tissue Removal Device for Fluent intended use is identical to the predicate MyoSure XL Tissue Removal Device and MyoSure Reach Tissue Removal Device.

**COMPARISON OF CHARACTERISTICS:**

The performance specifications and principles of operation of the modified MyoSure XL Tissue Removal Device for Fluent, including morcellator dimensions, cutting blade configuration, rotational speed, reciprocation rate, visualization, and access route to targeted tissue are identical to the predicate MyoSure XL Tissue Removal Device.

The mode of operation including method of use and mechanism of action, and material composition are also identical to the predicate MyoSure XL Tissue Removal Device.

The primary differences between the subject MyoSure XL Tissue Removal Device for Fluent and the predicate MyoSure XL Tissue Removal Device are as follows:

- The MyoSure XL Tissue Removal Device for Fluent does not require a button to adjust suction, while the predicate has an aspiration button to modulate the vacuum of fluid through the device
- The helix component of the internal drive mechanism was modified from a double helix to a single helix design.
- The internal O-Ring component was modified to include a white colorant.

All other components of the subject device are identical to the predicate device. The proposed modifications do not alter the fundamental scientific technology of the subject device and all performance specifications remain unchanged. The shelf-life, manufacturing process and packaging, and sterilization parameters are also the same.

The differences in technological characteristics do not raise different questions of safety and effectiveness.

**PERFORMANCE TESTING**

Biocompatibility

Material analysis and testing demonstrate the patient contacting materials are biocompatible and comply with the requirements of ANSI AAMI ISO 10993-1:2009:

- Cytotoxicity - ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Irritation - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Acute System Toxicity – ISO 10993-11:2006 – Part 11: Tests for systemic toxicity

Functional Testing

Non-clinical bench testing and simulated use testing demonstrate the MyoSure XL Tissue Removal Device for Fluent is substantially equivalent to the predicate device with regards to functional performance. Design verification testing demonstrated the subject device complies with the design specifications. Risk management activities in accordance with ISO 14971:2007 demonstrate the risks associated with the use of the MyoSure XL Tissue Removal Device for Fluent are mitigated to an acceptable level.

The following bench performance tests were conducted to assess the functional performance of the modified subject device:

- Connector Compatibility
- Cutting Performance
- Design verification (mechanical testing) of the handpiece
- Reciprocation Rate Test

The performance testing demonstrates that the performance of the MyoSure XL Tissue Removal Device for Fluent is substantially equivalent to the predicate device.

**CONCLUSION**

The modified subject device has the same intended use and fundamental technology as the predicate device. The performance data demonstrate the subject device is substantially equivalent to the predicate device.