DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 26, 2014

Hologic, Inc.
Sarah Fairfield
Sr. Regulatory Affairs Specialist
250 Campus Drive
Marlborough, MA 01752

Re: K142029
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 30, 2014
Received: October 31, 2014

Dear Sarah 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 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,

Herbert P. Lerner -S

for
Benjamin Fisher
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):

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

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

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)

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
Date Prepared: July 24, 2014

2. Device:

Trade Name: MyoSure Tissue Removal Device (part of the MyoSure Hysteroscopic Tissue Removal System)
Common Name: Hysteroscope and accessories
Classification Name: Hysteroscope and accessories (21 CFR 884.1690, Product Code HIH)
Class: II

3. Predicate Device:

TRUCLEAR Morcellator System and TRUCLEAR Morcellators (K132015)

4. Device Description:

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

- Tissue Removal Drive System
- Tissue Removal Device

The Myosure Hysteroscopic Tissue Removal System uses mechanical resection to remove endometrial polyps and submucous myomas 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.

5. Intended Use:

The Myosure Hysteroscopic Tissue Removal System 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 subject devices are intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps. The new proposed indications reword the general indication and specifically list retained products of conception.

6. Comparison of Characteristics:

There have been no major changes in design or materials in the subject Myosure Hysteroscopic Tissue Removal System or its associated tissue removal devices since their market clearance. As such, the technological characteristics have not changed.

The Myosure Hysteroscopic Tissue Removal System's intended use is identical to that of the predicate TRUCLEAR Morcellator System, K132015.

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

7. Performance Testing:

Clinical literature showcasing the use of mechanical morcellation support the use of the Myosure System for the proposed additional indications.

8. Conclusion:

Based on the intended use, descriptive information and clinical evaluation provided in this submission, the MyoSure Hysteroscopic Tissue Removal System has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate TRUCLEAR Morcellator system supporting the additional indications.