January 4, 2019

Polygon Medical, Inc.
% Christine Santagate
Director, Northeast Regional Operations
R&Q Solutions
15 Standish Rd
Norfolk, Massachusetts 02056

Re: K182675
Trade/Device Name: Polygon Resection Device
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH
Dated: December 4, 2018
Received: December 6, 2018

Dear Christine Santagate:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182675

Device Name
Polygon Resection Device

Indications for Use *(Describe)*
The Polygon Resection Device is intended for intrauterine use by a trained gynecologist to hysteroscopically resect and remove tissue, including focal lesions such as endometrial polyps and 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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510(K) SUMMARY

In accordance with 21 CFR 807.92(a) the following summary of information is provided:

Submitter Information

Submitter's Name:	Ronald Adams
	Polygon Medical, Inc.
Address:	18 Hillside Drive
	Holliston, MA 01746
Telephone:	775-800-7300
Fax:	844-225-4600
Contact Person:	Christine Santagate
Telephone :	339-237-8122

Date Prepared:	January 2, 2019
Device Trade Name:	Polygon Resection Device
Common/Usual Name:	Hysteroscopic Tissue Removal Device
Class:	II
Product Code(s):	HIH, Hysteroscope and Accessories
Regulation Number(s):	884.1690 (Hysteroscope and Accessories)

Predicate Device(s):
K173901
Device Name: MyoSure MANUAL Tissue Removal Device
Manufacturer: Hologic, Inc.

The predicate device has not been subject to a design related recall.

Device Description:

The Polygon Resection Device is a handheld manually operated device designed for the hysteroscopic removal of intrauterine tissue. The device is provided sterile. The shaft of the device is design to fit into the working channel of any hysteroscope that includes a 3.0 mm (Fr) straight working channel.

The device is activated by the physician by squeezing the trigger. A rotation knob is provided to enable the physician to rotate the cutting bay into an orientation that aligns with the desired specimen. The barb fitting provides an attachment port for a vacuum system. The vacuum system pulls the specimen into the cutting window where it can be resected and aspirated out of the patient.

There are no electrical or powered connections necessary for operation of the device.

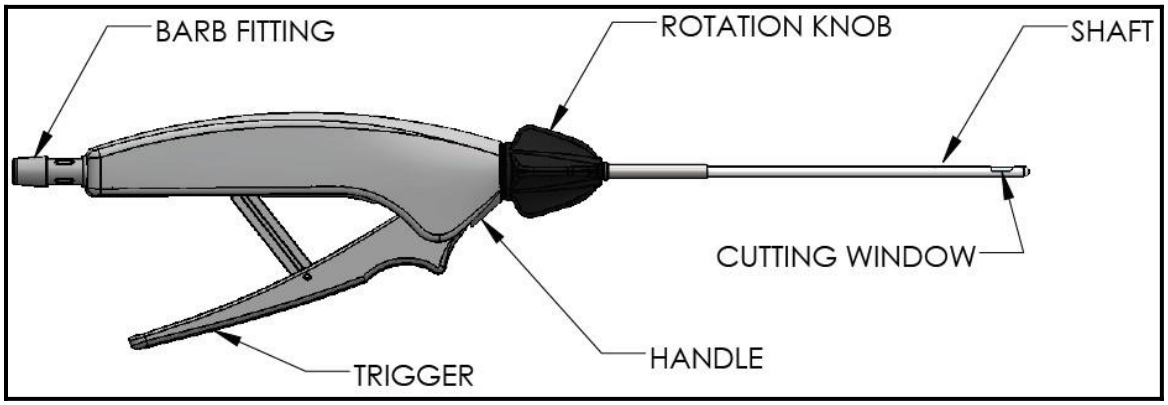

Figure 1. Polygon Resection Devic

Indications for Use:
The Polygon Resection Device is intended for intrauterine use by a trained gynecologist to hysteroscopically resect and remove tissue, including focal lesions such as endometrial polyps and retained products of conception.

The subject device intended use is identical to the predicate device.

Comparison of Technological Characteristics:

The Polygon Resection Device is similar in design, materials, and construction to the Hologic Myosure Manual (predicate device). The principal of operation for both devices is the same.

The primary differences between the subject and predicate devices are as follows:

- The morcellator working length is 36cm for the subject device vs. 32cm for the predicate device.
- The cutting window dimensions are 7mm for the subject device vs. 10mm for the predicate device.
- The subject device has an in-line trigger orientation, while the predicate device has a perpendicular trigger design.
- The subject and predicate devices contain different patient-contacting materials.

These differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

Non-Clinical Testing Summary:
The following data were provided to demonstrate substantial equivalence and functional performance of the subject device:

- Sterilization validation was conducted in accordance with ISO 11135-1: 2014.

- Shelf life validation testing was conducted including package integrity testing and functional testing.

- Biocompatibility evaluation in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
    - Cytotoxicity testing
    - Guinea Pig Maximization Sensitization testing
    - Irritation testing
    - Acute Systemic Toxicity testing

- Design verification testing:
    - Joint connection strength
    - Visual Inspection
    - Tissue trap removal force

- Functional performance testing was conducted in a simulated use model:
    - Hysteroscope compatibility
    - Vacuum system compatibility
    - Device cutting performance (successful removal of tissue without clogging, cutting rate, and fluid usage)

All test samples met the acceptance criteria for each test.

Clinical Usability Testing Summary:
Usability and human factors were assessed through a clinical usability study. The subject device was used to remove intrauterine tissue by five physicians with a range of experience in a total of 32 cases. The usability study evaluated ease of use, successful removal of tissue without clogging, and number of device activations required to complete the procedure. The usability testing demonstrated the subject device can be used per the Instructions for Use as intended.

Conclusion:

Based on the intended use, descriptive information and performance provided in this submission, the Polygon Resection Device has been shown to be substantially equivalent to the predicate MyoSure Manual Tissue Removal Device.