September 25, 2020

Stryker Sustainability Solutions
Scott English
Senior Staff Regulatory Affairs Specialist
1810 W. Drake Drive
Tempe, AZ 85283

Re: K201756
Trade/Device Name: Reprocessed MyoSure Tissue Removal Device (10-401/10-403), Reprocessed MyoSure REACH Tissue Removal Device (10-401FC/10-403FC), Reprocessed MyoSure LITE Tissue Removal Device (30-401LITE/30-403LITE), Reprocessed MyoSure XL Tissue Removal Device (50-501XL/50-503XL), Reprocessed MyoSure XL Tissue Removal Device for Fluent (50-601XL/50-603XL)
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: June 27, 2020
Received: June 29, 2020

Dear Scott English:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K201756

Device Name
Reprocessed MyoSure Tissue Removal Device (10-401/10-403), Reprocessed MyoSure REACH Tissue Removal Device (10-401FC/10-403FC), Reprocessed MyoSure LITE Tissue Removal Device (30-401LITE/30-403LITE), Reprocessed MyoSure XL Tissue Removal Device (50-501XL/50-503XL), Reprocessed MyoSure XL Tissue Removal Device for Fluent (50-601XL/50-603XL)

Indications for Use *(Describe)*
The Reprocessed MyoSure Tissue Removal Device (Model # 10-401/10-403) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retained products of conception.

The Reprocessed MyoSure REACH Tissue Removal Device (Model # 10-401FC/10-403FC) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain products of conception.

The Reprocessed MyoSure LITE Tissue Removal Device (Model # 30-401LITE/30-403LITE) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain products of conception.

The Reprocessed MyoSure XL Tissue Removal Device (Model # 50-501XL/50-503XL) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain products of conception.

The Reprocessed MyoSure XL Tissue Removal Device for Fluent (Model # 50-601XL/50-603XL) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain 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

Submitter:
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Date of Preparation: June 27, 2020

Name of Device:

Trade/Proprietary Name	Model Number
Reprocessed MyoSure Tissue Removal Device	10-401/10-403
Reprocessed MyoSure REACH Tissue Removal Device	10-401FC/10-403FC
Reprocessed MyoSure LITE Tissue Removal Device	30-401LITE/30-403LITE
Reprocessed MyoSure XL Tissue Removal Device	50-501XL/50-503XL
Reprocessed MyoSure XL Tissue Removal Device for Fluent	50-601XL/50-603XL

Common Name: Hysteroscope and Accessories

Classification Information: Hysteroscope and Accessories (21 CFR § 884.1690, HIH, Class II)

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
10-401 10-403	K172566	MyoSure Hysteroscopic Tissue Removal System and MyoSure Tissue Removal Devices	Hologic, Inc.
10-401FC 10-403FC	K152723	MyoSure Hysteroscopic Tissue Removal System and MyoSure Tissue Removal Devices	Hologic, Inc.
30-401LITE 30-403LITE	K172566	MyoSure Hysteroscopic Tissue Removal System and MyoSure Tissue Removal Devices	Hologic, Inc.
50-501XL 50-503XL	K172566	MyoSure Hysteroscopic Tissue Removal System and MyoSure Tissue Removal Devices	Hologic, Inc.
50-601XL 50-603XL	K181974	MyoSure XL Tissue Removal Device for Fluent	Hologic, Inc.

The predicate devices have not been subject to a design-related recall.

Device Description:

The Reprocessed MyoSure Tissue Removal Devices are sterile, disposable, hand-held tissue

removal devices that are used to hysteroscopically remove intrauterine tissue. The devices are connected via a 6-foot (1.8-meter) flexible drive shaft to a motorized control unit. A foot pedal allows the user to control the cutting action of the tissue removal device by turning the motor in the control unit on and off. The proximal end of the 10-foot (3-meter) vacuum tubing is connected to a collection canister. The devices use mechanical resection by drawing the tissue through the cutting window under suction, while the inner blade simultaneously rotates and reciprocates to cut the tissue.

Device Specifications					
Model	**Outer Diameter**	**Working Length**	**Window Length**	**Window Depth**	**Window Size**
Reprocessed MyoSure	3 mm	32 cm	14.0 mm	1.8 mm	54 mm^3
Reprocessed MyoSure REACH	3 mm	32 cm	14.0 mm	1.8 mm	54 mm^3
Reprocessed MyoSure LITE	3 mm	32 cm	10.2 mm	1.5 mm	31 mm^3
Reprocessed MyoSure XL	4 mm	32 cm	14.0 mm	2.4 mm	98 mm^3
Reprocessed MyoSure XL-Fluent	4 mm	32 cm	14.0 mm	2.4 mm	98 mm^3

Indication for Use:

The Reprocessed MyoSure Tissue Removal Device (Model # 10-401/10-403) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retained products of conception.

The Reprocessed MyoSure REACH Tissue Removal Device (Model # 10-401FC/10-403FC) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain products of conception.

The Reprocessed MyoSure LITE Tissue Removal Device (Model # 30-401LITE/30-403LITE) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain products of conception.

The Reprocessed MyoSure XL Tissue Removal Device (Model # 50-501XL/50-503XL) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain products of conception.

The Reprocessed MyoSure XL Tissue Removal Device for Fluent (Model # 50-601XL/50-603XL) is indicated for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retain products of conception.

The indications for use are the same as the predicate devices.

Comparison of Technological Characteristics:

The principles of operation and primary functional specifications of the Reprocessed MyoSure Tissue Removal Devices are identical to those of the predicate MyoSure Tissue Removal Devices. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. The only differences between the Reprocessed MyoSure Tissue Removal Devices and the predicate devices MyoSure Tissue Removal Devices is that devices are reprocessed, and some device components are replaced with equivalent components during the reprocessing operation.

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

Performance Data:

Bench and laboratory testing were conducted to demonstrate performance (safety and effectiveness) of the Reprocessed MyoSure Tissue Removal Device. This included the following tests:

Biocompatibility

The biocompatibility evaluation for the Reprocessed MyoSure Tissue Removal Devices was conducted in accordance with FDA Guidance Document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" dated June 16, 2016, and International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Materials Mediated Pyrogenicity
- Chemical Characterization

The Reprocessed MyoSure Tissue Removal Devices are considered surface contacting, applied to breached surfaces for a duration of less than 24 hours.

Validation of Reprocessing

The reprocessing validation was derived from the recommendations of AAMI/TIR 30:2011, "A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices"; ASTM D7225-13:2013, "Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors; AAMI/TIR 12:2010: Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers"; AAMI/ANSI ST35:2003, "Safe handling and biological decontamination of medical devices in health care facilities and in non-clinical settings"; ISO/TS 15883-5, "Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy", and ASTM F3208-18, "Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices."

Sterilization and Shelf Life

Sterility of the Reprocessed MyoSure Tissue Removal Devices was assessed in accordance with ANSI/AAMI/ISO 11135-1:2014, “Sterilization of Health Care Products – Ethylene oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.”
Shelf Life verification testing included assessment of package integrity and device functional performance following aging.

Electrical Safety
Electrical safety testing was conducted on the Reprocessed MyoSure Tissue Removal Devices. The devices comply with the IEC 60601-1 standard for safety.

Functional Performance
- Shaft deflection
- Leak decay
- Drive cable plug insertion
- Shaft insertion force
- Torque
- Linearity
- Revolutions Per Minute
- Reciprocation
- Wear particulate
- Bend
- Tissue cutting and removal performance
- Reliability testing
- Device functional attribute tests
- Equipment compatibility

The bench testing involved evaluation of the devices’ performance and ability to cut and resect tissue. The results of the evaluations demonstrate that the Reprocessed MyoSure Tissue Removal Devices effectively cut and resect tissue in accordance with the intended use.

Conclusion:

The results of bench testing and laboratory evaluations demonstrate that the Reprocessed MyoSure Tissue Removal Devices are at least as safe and effective and perform as well as the identified legally marketed predicate devices as described herein.