December 6, 2018

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

Re: K182006
Trade/Device Name: Omni Hysteroscope – Omni Hysteroscope (60-200), Omni 3.7 mm Diagnostic Sheath (60-201), Omni 5.5 mm Operative Sheath (60-202), Omni 6 mm Operative Sheath (60-203), Operating Room set (60-205-1), Office set (60-250-2)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH
Dated: November 8, 2018
Received: November 9, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182006

Device Name
Omni Hysteroscope - Omni hysteroscope (60-200), Omni 3.7 mm Diagnostic Sheath (60-201), Omni 5.5mm Operative Sheath (60-202), Omni 6mm Operative Sheath (60-203), Operating Room set (60-250-1), Office set (60-250-2)

Indications for Use *(Describe)*
The Omni Hysteroscope is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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: November 8, 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: Omni Hysteroscope - Omni hysteroscope (60-200), Omni 3.7 mm Diagnostic Sheath (60-201), Omni 5.5mm Operative Sheath (60-202), Omni 6mm Operative Sheath (60-203), Operating Room set (60-250-1), Office set (60-250-2)

Common/Usual Name: Hysteroscope

Regulation Name: Hysteroscope and Accessories

Regulation Number: 21 CFR 884.1690

Product Code: HIH, Hysteroscope and Accessories

Classification: Class II

Panel: Obstetrics/Gynecology

PREDICATE DEVICES

Tradename: MyoSure XL Rod Lens Hysteroscope
Submitter/510(k) Holder: Hologic, Inc.
510(k) #: K122563
Product Code: HIH
Regulation: 21CFR 884.1690

Tradename: MyoSure Rod Lens Hysteroscope
Submitter/510(k) Holder: Hologic, Inc.
510(k) #: K091465
Product Code: HIH
Regulation: 21CFR 884.1690

The MyoSure and MyoSure XL Rod Lens Hysteroscopes have not been subject to a design-related recall.

DEVICE DESCRIPTION

The Omni Hysteroscope is used to provide viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedure. The Omni Hysteroscope is a

hysteroscope consisting of a (base) rigid hysteroscope with optics and lighting connections. The Omni Hysteroscope includes three compatible sheaths, one diagnostic and two operative, that attach to the base scope; Omni 3.7 mm Diagnostic Sheath, Omni 5.5 mm Operative Sheath, and Omni 6mm Operative Sheath. The Omni Hysteroscope also includes removable outflow channels for fluid drainage.

The Omni Hysteroscope is supplied non-sterile and is designed for multiple use with the device being cleaned and sterilized prior to each use.

INDICATIONS FOR USE:
The Omni Hysteroscope is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

The Omni Hysteroscope intended use is identical to the predicates MyoSure and MyoSure XL Hysteroscopes.

TECHNOLOGICAL CHARACTERISTICS:

Primary specifications for the Omni Hysteroscope including light source, thermal and electrical safety are identical to the predicate MyoSure and MyoSure XL Hysteroscope. The hysteroscope dimensions and materials of construction in the Omni Hysteroscope are similar to the predicate MyoSure and MyoSure XL Rod Lens Hysteroscope.

The mode of operation including method of use and mechanism of action, are identical to the predicate MyoSure XL Rod Lens Hysteroscope and are similar to the secondary predicate MyoSure Rod Lens Hysteroscope.

The primary differences between the proposed Omni Hysteroscope and the predicate MyoSure and MyoSure XL Rod Lens Hysteroscopes are as follows:

- The Omni Hysteroscope does not have an integrated working channel as the predicates do. Rather the subject devices have removable sheaths for the working channels of the Omni Hysteroscope.
- The Omni Hysteroscope utilizes simlar materials of construction as the predicate hysteroscopes with the addition of polyphenylsulfone (PPSU) and black, blue, and green colorants.
- The working length of the Omni Hysteroscope is longer than the predicates MyoSure and MyoSure XL Rod Lens Hysteroscopes.
- The outer diameters of the Omni Hysteroscope 3.7mm diagnostic sheath and 5.5mm operative sheath are smaller than the outer diameter of the predicate MyoSure Rod Lens Hysteroscope.
- The outer diameter of the Omni Hysteroscope 6 mm operative sheath is smaller than the outer diameter predicate MyoSure XL Rod Lens Hysteroscope.

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

Characteristic	Omni Hysteroscope	Primary Predicate Device (K122563)	Secondary Predicate Device (K091465)
Intended Use	The Omni Hysteroscope is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.	The MyoSure Rod Lens Hysteroscope is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.	
Prescription Only	Yes	Same	Same
Design	Rigid Hysteroscope	Same	Same
Patient Contacting Materials	Stainless steel, Sapphire, Optical Glass, PEEK, Glass Fiber, PPSU (black, blue, and green colorant), Nickel Silver	Stainless steel, Sapphire, Optical Glass, PEEK, Glass Fiber, PPSU,Nickel Silver	Stainless steel, Sapphire, Optical Glass, PEEK, Glass Fiber, Nickel Silver
Working length	200 mm	184 mm	184 mm
Outer diameter	3.7-4.8 mm x 3.7- 7.5 mm	6.5 x 7.6 mm	6.0 x 6.4 mm
Light Source	Metal Halide or Xenon ≤300w	Same	Same
Biocompatibility	According to ANSI AAMI ISO 10993-1:2009	Same	Same

PERFORMANCE TESTING

Design verification testing demonstrates devices comply with design specifications. Design verification testing of the Omni Hysteroscope included:

- Dimensional verification
- Objective lens testing (Field of view, focal length, depth of field, direction of view)
- Level of Illumination
- Luminous Energy Transmission Ratio
- Magnification (eyepiece)
- Image Quality (Resolution, Distortion)

Risk management activities in accordance with ISO 14971:2007 demonstrate the risks associated with the use of the Omni Hysteroscope are mitigated to an acceptable level. Analyses of these activities indicate the benefits associated with the use of the Omni Hysteroscope outweigh the residual risks. Material analysis and testing demonstrate the patient contacting materials are biocompatible and comply with the requirements of ANSI AAMI ISO 10993-1:2009. Electrical safety testing was performed and passed ANSI AAMI ES 60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 and IEC 60601-2-18:2009. Usability testing was conducted in accordance with the FDA Guidance, Applying Human Factors and Usability Engineering to Medical Devices, issued on February 3, 2016 and IEC 62366-1:2015 Medical Devices – Part 1: application of usability engineering to medical devices. A cleaning validation of the Omni Hysteroscope was successfully performed and sterilization validations of the Omni hysteroscope were conducted in accordance with ISO 14937:2009/(R)2013 Sterilization of health care products - General requirements

for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices and ANSI/AAMI/ISO 17665-1:2006/(R)2013 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. Performance testing demonstrates that the performance of the Omni Hysteroscope is substantially equivalent to the predicate devices.

CONCLUSION

Based on the intended use, descriptive information and performance provided in this submission, the Omni Hysteroscope has been shown to be substantially equivalent to the predicate MyoSure and MyoSure XL Rod Lens Hysteroscopes.