August 29, 2019

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

Re: K191281
Trade/Device Name: Omni Hysteroscope, Omni Lok cervical seal
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, QHZ
Dated: July 26, 2019
Received: July 29, 2019

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/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,

Sharon Andrews
Assistant Division 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)*
K191281

Device Name
Omni hysteroscope

Omni Lok cervical seal

Indications for Use *(Describe)*
Omni hysteroscope:
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.

Omni Lok cervical seal:
The Omni Lok cervical seal is used during a hysteroscopic procedure to minimize liquid distention media leakage from the cervix.

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

Date Prepared: August 27, 2019

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
Common/Usual Name: Hysteroscope
Regulation Name: Hysteroscope and accessories
Regulation Number: 21 CFR 884.1690
Product Code: HIH
Classification: Class II
Panel: Obstetrics/Gynecology

Trade Name: Omni Lok cervical seal
Common/Usual Name: Hysteroscope accessory
Regulation Name: Hysteroscope and accessories
Regulation Number: 21 CFR 884.1690
Product Code: QHZ
Classification: Class I, exempt
Panel: Obstetrics/Gynecology

PREDICATE DEVICE

Tradename: Omni hysteroscope
Submitter/510(k) Holder: Hologic, Inc.
510(k) #: K182006
Product Code: HIH
Regulation: 21 CFR 884.1690

The Omni hysteroscope has 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 procedures. 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.

The Omni hysteroscope can be used with the Omni Lok cervical seal accessory. The Omni Lok cervical seal accessory slides over the operative sheath of the Omni hysteroscope. The Omni Lok cervical seal accessory is intended to be used during a hysteroscopic procedure to minimize liquid distention media leakage from the cervix.

The Omni Lok cervical seal is a sterile, single – use accessory for hysteroscopic procedures. The Omni Lok cervical seal remains seated at the opening of the cervix and remains flush against the cervical opening throughout the duration of the procedure to create a seal. This seal minimizes fluid leakage from the cervix.

INDICATIONS FOR USE:

Omni hysteroscope:

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 indications for use is identical to the predicate Omni hysteroscope.

Omni Lok cervical seal:

The Omni Lok cervical seal is used during a hysteroscopic procedure to minimize liquid distention media leakage from the cervix.

TECHNOLOGICAL CHARACTERISTICS:

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

The mode of operation including method of use, materials of construction, and mechanism of action, are identical to the predicate Omni hysteroscope.

The primary differences between the proposed Omni Hysteroscope and the predicate Omni hysteroscope is the addition of the optional Omni Lok cervical seal accessory.

Omni Lok cervical seal:
The Omni Lok cervical seal accessory slides over the operative sheath of the hysteroscope to minimize liquid distention media leakage from the cervix during a hysteroscopic procedure.

The Omni Lok cervical seal utilizes a compliant silicone tip to press against the cervix to form a fluid

seal. The silicone tip connects to a white sleeve, holding a spring, and a blue collar and white base. The blue collar and white base can extend the device to the "Extended" position if needed. The spring allows for the seal position to be maintained, as needed, through movement of the hysteroscope during procedures.

The difference of adding the optional Omni Lok cervical seal accessory does not raise any different questions of safety and effectiveness.

Characteristic	**Proposed Omni Hysteroscope**	**Primary Predicate Device (K182006)**
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	
Prescription Only	Yes	Same
Design	Rigid Hysteroscope	Same
Patient Contacting Materials	Stainless steel, Sapphire, Optical Glass, PEEK, Glass Fiber, PPSU (black, blue, and green colorant), Nickel	Same
Working length	200 mm	Same
Outer diameter	3.7-4.8 mm x 3.7- 7.5 mm	Same
Light Source	Metal Halide or Xenon ≤300w	Same
Biocompatibility	According to ANSI AAMI ISO 10993-1:2009	Same
Compatible with Omni Lok cervical seal	Yes	N/A

PERFORMANCE TESTING

There have been no changes to the Omni hysteroscope performance as a result of this submission. The testing submitted in the predicate K182006 showed the device complies with all design specifications.

The Omni Lok cervical seal accessory was evaluated through non-clinical bench testing and simulated use testing related to materials, technology and performance. Design verification of the Omni Lok cervical seal included:

- Shelf life testing in accordance with ASTM F1980-16
    - The device was demonstrated to maintain specifications for an equivalent of 6 months real-time shelf life
- Biocompatibility testing:
    - Cytotoxicity per ISO 10993-5:2009
        - Device was demonstrated to be non-cytotoxic
    - Vaginal irritation per ISO 10993-10:2010
        - Device was demonstrated to be non-irritating
    - Guinea Pig Maximization Sensitization per ISO 10993-10:2010
        - Device was demonstrated to be non-sensitizing
- Environmental/Transit conditioning to ASTM D4169-16:DC 13, AL 2 and package integrity per ISO 11607-1:2006 and ASTM F2086-11
    - Device packaging was demonstrated to maintain integrity after simulated distribution

and aging

- Sterilization validation per ISO 11135:2014
- Usability testing to IEC 62366-1:2015
- Design verification testing per in-house methods as noted in the table below:

Test Name	Results
Friction fit test	Pass
Spring compression testing	Pass
Leak testing	Pass
Extended Position Force Test	Pass
Device length test	Pass
Tip attachment test	Pass

The verification test results demonstrate the device functions as intended; i.e., the device specifications are met, the device adequately attaches to the hysteroscope, has appropriate mechanical properties, and reduces leakage from a model cervix/uterus when utilized with a hysteroscope.

CONCLUSION

Based on the intended use, descriptive information and performance testing provided in this submission, the Omni hysteroscope and Omni Lok cervical seal accessory have been demonstrated to be substantially equivalent to the predicate Omni hysteroscope.