February 26, 2019

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

Re: K182052
Trade/Device Name: Omni Instrument Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: January 29, 2019
Received: January 25, 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/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,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K182052

Device Name
Omni Instrument Tray

Indications for Use *(Describe)*
The Omni Instrument Tray is intended to enclose, protect, and organize the Omni Hysteroscope, Sheaths, and Removable Outflow Channels during sterilization and storage.

The Omni Instrument Tray must be used in conjunction with a sterilization wrap that is cleared by FDA for the indicated sterilization cycles.

The Omni Instrument Tray has been validated for the following sterilization cycles:

Prevacuum Steam	STERRAD®
132°C (270°F) 4 minutes exposure 35 minutes dry time	- STERRAD 100S Short - STERRAD NX Standard - STERRAD 100NX Standard
Contents: - 1 Omni Hysteroscope - 1 Removable Outflow Channel - 1 XL Removable Outflow Channel - 1 Omni 3.7mm Diagnostic Sheath - 1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters	Contents: - 1 Omni Hysteroscope - 1 Removable Outflow Channel - 1 XL Removable Outflow Channel - 1 Omni 3.7mm Diagnostic Sheath - 1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters

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 K182052

Date: February 20, 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 Instrument Tray

Common/Usual Name: Sterilization Tray

Regulation Name: Sterilization wrap

Regulation Number: 21 CFR 880.6850

Product Code: KCT

Classification: Class II

Panel: General Hospital

PREDICATE DEVICE

Tradename: MyoSure Instrument Tray
Submitter/510(k) Holder: Hologic, Inc.
510(k) #: K121280
Product Code: KCT
Regulation: 21CFR 880.6850

DEVICE DESCRIPTION

The Omni Instrument Tray is intended to enclose, protect, and organize The Omni Hysteroscope, Sheaths, and Removable Outflow Channels during sterilization and storage.

The Omni Instrument Tray must be used in conjunction with a sterilization wrap that is cleared by FDA for the indicated sterilization cycles.

The Omni Instrument Tray is made of a stainless steel, santoprene, and silicone and is supplied non-sterile and is designed for multiple use for the sterilization of the Omni Hysteroscope set prior to each use of the Hysteroscope.

The Omni Instrument Tray has been validated for the following sterilization cycles:

Pre-vacuum Steam	STERRAD®
132°C (270°F) 4 minutes exposure 35 minutes dry time	STERRAD NX™ Standard STERRAD 100NX™ Standard STERRAD 100S Short
Contents: - 1 Omni Hysteroscope -1 Removable Outflow Channel -1 XL Removable Outflow Channel -1 Omni 3.7mm Diagnostic Sheath -1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters	Contents: - 1 Omni Hysteroscope -1 Removable Outflow Channel -1 XL Removable Outflow Channel -1 Omni 3.7mm Diagnostic Sheath -1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters

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The Omni Instrument Tray is intended to enclose, protect, and organize The Omni Hysteroscope, Sheaths, and Removable Outflow Channels during sterilization and storage.

The Omni Instrument Tray must be used in conjunction with a sterilization wrap that is cleared by FDA for the indicated sterilization cycles.

The Omni Instrument Tray has been validated for the following sterilization cycles:

Pre-vacuum Steam	STERRAD®
132°C (270°F) 4 minutes exposure 35 minutes dry time	STERRAD NX™ Standard STERRAD 100NX™ Standard STERRAD 100S Short
Contents: - 1 Omni Hysteroscope -1 Removable Outflow Channel -1 XL Removable Outflow Channel -1 Omni 3.7mm Diagnostic Sheath -1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters	Contents: - 1 Omni Hysteroscope -1 Removable Outflow Channel -1 XL Removable Outflow Channel -1 Omni 3.7mm Diagnostic Sheath -1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters

TECHNOLOGICAL CHARACTERISTICS:

Technological Characteristic	**Omni Instrument Tray**	**Predicate Device (K121280)**	**Reference Device (K171692)**
Intended Use	The tray is intended to enclose, protect, and organize medical devices.	The tray is intended to enclose, protect, and organize medical devices.	The tray is intended to enclose, protect, and organize medical devices.
Biocompatibility	Steam Autoclave Pre-Vacuum 132°C (270°F); 4 min Exposure; 35 min dry time STERRAD NX Standard STERRAD 100NX Standard STERRAD 100S Short Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Test for in vitro cytotoxicity. Under the condition of the study, the device extract was found not to be cytotoxic to the testing assay.	Steam Autoclave; Pre-Vacuum 132°C (270°F), 4 min Exposure, 30 min dry time; STERRAD® 100S Short cycle Hemolytic Test 10993-4 Biological evaluation of medical devices-Part: Selection of tests for interactions with blood; Irritation 10993-10: Tests for irritation and skin sensitization. Under the conditions of the study, device extract was found not to be hemolytic to the testing assay. Under the conditions of the study, the polar and non-polar device extracts were found not to be a sensitizer nor an irritant to the animal model.	Steam Autoclave; Pre-Vacuum 132°C (270°F), 3 min Exposure, 15-30 min dry time; STERRAD: NX Standard and Express, 100S Short Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Test for in vitro cytotoxicity. Under the condition of the study, the device extract was found not to be cytotoxic to the testing assay.

Technological Characteristic	**Omni Instrument Tray**	**Predicate Device (K121280)**	**Reference Device (K171692)**
Prescription Only	No	No	No
Device Description	Stainless Steel tray and lid with metal lid locking mechanism and handles Accessories include: silicone grommets, and stainless steel posts	Fenestrated plastic tray and lid with metal lid locking mechanism and handles Accessories include: silicone grommets, and stainless steel posts	Rigid containment device consisting of a base with a lid which can be fastened by a latching mechanism. The device is perforated in order to enable reprocessing of enclosed medical devices held in place by silicone retainers.
Materials of construction • Tray • Lid • Handles/ Latching • Grommets	• Stainless Steel/ Santoprene • Stainless Steel • Stainless Steel/ Silicone/Santoprene • Silicone	• Radel®R resin • Radel®R resin • Stainless Steel • Silicone	• Stainless steel • Stainless steel • Stainless Steel • Silicone
Dimensions • Length • Width • Height	• 16.20” • 10.11” • 2.27”	• 13.45” • 8.41” • 2.00”	• 22.83” • 3.03” • 10.63”
Sterilization cycles	Steam Autoclave: Pre-Vacuum 132°C (270°F); 4 min Exposure; 35 min dry time STERRAD NX Standard STERRAD 100NX Standard STERRAD 100S Short	Steam Autoclave Pre-Vacuum 132°C (270°F), 4 min Exposure, 30 min dry time; STERRAD® 100S Short cycle	Steam Autoclave Pre-Vacuum 132°C (270°F), 3 min Exposure, 15-30 min dry time; STERRAD: NX Standard and Express, 100S Short
Capacity (Maximum total weight)	25 lbs	13 lbs	8.708 lbs
Reusable	Yes	Yes	Yes
Perforations (Vent to Volumne Ratio)	.435 in^2/in^3	.020 in^2/in^3	72%

Technological Characteristic	Omni Instrument Tray	Predicate Device (K121280)	Reference Device (K171692)
Patient Contacting Materials	None	None	None

PERFORMANCE TESTING

Clinical Testing

No clinical testing was performed, submitted, referenced or relied upon for the Omni Instrument Tray.

Bench Testing

Non-clinical bench testing and simulated use testing demonstrate the Omni Instrument Tray is similar to the predicate device. Design verification testing included:

- Biocompatibility testing to ISO 10993-5:2009 (Biological evaluation of medical devices-Part 5: Test for in vitro cytotoxicity)
- Usability testing to IEC 62366-1:2015 (Medical devices-Part 1: Application of usability engineering to medical devices)
- Packaging testing to ISTA 3A (Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb or less)
- Design verification testing to hold the Omni hysteroscope, Sheaths, and Removable Outflow Channels (ANSI/AAMI ST77:2013 Containment devices for reusable medical device sterilization)
    - Attribute verification of component fit
- Reliability testing including durability, drop test, and handle strength (AAMI TIR12:2010 Design, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers)
    - Latch cycle durability
    - Simulated table height drop test
    - Handle pull strength to sustained load

Cleaning and Sterilization

The Omni Instrument Tray is supplied non-sterile and required processing through cleaning and sterilization at the health care facility by the end user. Validation testing confirmed the methods and parameters of these processes as specified in the device labeling.

The following standards were used during the validation process:

Standard Reference	Standard Title
AAMI/ANSI ST79:2017	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ANSI/AAMI ST77:2013	Containment devices for reusable medical device sterilization
ISO 17664:2017	Processing Of Health Care Products - Information To Be Provided By The Medical Device Manufacturer For The Processing Of Medical Devices
ISO 17665-1:2006	Sterilization Of Health Care Products - Moist Heat - Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ISO TS 17665-2:2009	Sterilization Of Health Care Products - Moist Heat - Part 2: Guidance On The Application Of ISO 17665-1
ANSI/AAMI/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
AAMI TIR12:2010	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR30:2011	A compendium of processes, materials, test methods, acceptance criteria for cleaning reusable medical devices

The above referenced design verification testing and cleaning and sterilization validations demonstrate the subject device met the design specifications.

CONCLUSION

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device MyoSure Instrument Tray (K121280).