5. 510(k) SUMMARY

OCT 17 2012

1. Submitter:

Hologic, Inc.
250 Campus Dr.
Marlborough, MA 01752
Telephone: 508.263.8857

Contact: Sarah Fairfield, Sr. Regulatory Affairs Specialist

2. Device:

Trade Name: THS Sterilization Tray
Common Name: Instrument Sterilization Tray and Accessories
Classification Name: 880.6850 Sterilization Wrap
Product Code: KCT
Class: II

3. Predicate Device:

Tradename: PolyVac Surgical Instrument Delivery System
Submitter / 510(k) Holder: Symmetry Medical, Inc.
510(k) #'s: K012105 and K040223

4. Device Description:

The THS Sterilization Tray will secure the reusable THS components during autoclave sterilization in preparation for future procedures. The THS Sterilization Tray described in this submission contains no components or materials that directly contact the patient and/or patient body fluids.

5. Intended Use:

The THS Sterilization Tray is used to enclose, protect, and organize the THS scopes, diagnostic sheath, and associated accessory components, and to facilitate the sterilization process by allowing sterilant penetration and air removal when used in conjunction with an approved sterilization wrap.

The THS Sterilization Tray is not designed to maintain sterility by itself, but when used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.

The THS Sterilization Tray is to be sterilized using one of the following cycles:

Steam Autoclave Wrapped	
Pre-Vacuum Parameters:	270°F for 4 minutes
Pre-Vacuum Dry Time:	30 minutes
Gravity Parameters:	250°F for 30 minutes
Gravity Dry Time:	30 minutes

6. Comparison of Characteristics:

The design, principles of operation, primary functional specifications and materials of composition of the THS Sterilization Tray are identical to those of the predicate PolyVac Surgical Instrument Delivery System (Standard Modultainer - ¾ size system and accessories) in that:

- all trays are fabricated from identical plastic and/or metal materials,
- all trays are autoclavable and reusable,
- both the THS and PolyVac devices are identical in dimension and design features.

The THS Sterilization Tray's intended use is identical to that of the predicate PolyVac Surgical Instrument Delivery System (K012105 and K040223).

7. Performance Testing:

The THS Sterilization Tray has been validated to be sterilized using one of the following cycles:

Steam Autoclave Wrapped	
Pre-Vacuum Parameters:	270°F for 4 minutes
Pre-Vacuum Dry Time:	30 minutes
Gravity Parameters:	250°F for 30 minutes
Gravity Dry Time:	30 minutes

8. Conclusion:

Based on the intended use, descriptive information and performance evaluation provided in this submission, the THS Sterilization Tray has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate PolyVac Surgical Instrument Delivery System (Standard Modultainer - ¾ size system and accessories).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hologic, Incorporated
Ms. Sarah Fairfield
Senior Regulatory Affairs Specialist
250 Campus Drive
Marlborough, Massachusetts 01752

OCT 17 2012

Re: K120947
Trade/Device Name: THS Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: September 27, 2012
Received: September 27, 2012

Dear Ms. Fairfield:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K120947

Device Name: THS Sterilization Tray

Indications For Use:

The THS Sterilization Tray is used to enclose, protect, and organize the THS scopes, diagnostic sheath, and associated accessory components, and to facilitate the sterilization process by allowing sterilant penetration and air removal when used in conjunction with an approved sterilization wrap.

The THS Instrument tray is not designed to maintain sterility by itself, but when used in conjunction with an approved sterilization wrap sterility of the enclosed medical device is maintained based on the specific time that the maintenance of sterility for that specific wrap as cleared by the FDA.

The THS Sterilization Tray is to be sterilized using one of the following cycles:

Steam Autoclave Wrapped	
Pre-Vacuum Parameters:	270°F for 4 minutes
Pre-Vacuum Dry Time:	30 minutes
Gravity Parameters:	250°F for 30 minutes
Gravity Dry Time:	30 minutes

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120947