January 2, 2021

O&M Halyard, Inc
Steven Dowdley
Associate Director of Regulatory Affairs
1 Edison Drive
Alpharetta, Georgia 30005

Re: K203177
Trade/Device Name: Sterisystem Dry-Base Instrument Tray
Regulation Number: 21 CFR 880.6250
Regulation Name: Sterilization Tray
Regulatory Class: Class II
Product Code: KCT
Dated: November 12, 2021
Received: November 12, 2021

Dear Steven Dowdley:

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,

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K203177

Device Name
Sterisystem Dry-Base Instrument Tray

Indications for Use *(Describe)*

The Sterisystem Dry-Base Instrument Tray is intended to protect surgical instruments and facilitate the sterilization process by sterilant penetration and air removal. When used in conjunction with an FDA cleared sterilization wrap, sterility of the enclosed medical device is maintained until used.

The alone trays are not intended to maintain sterility; they are intended to be used in conjunction with an FDA cleared sterilization wrap in order to maintain sterility of the enclosed devices.

The system has been validated for the use in the following sterilization cycle:
Pre-Vacuum Steam
Temperature: 132C (270F)
Sterilization Time: 4 minutes
Drying time: 30 minutes
Maximum Weight: Up to 25lbs depending on the weight limit of the cleared sterilization wrap used.

Pre-Vacuum sterilized devices may be stored in a protective storage for up to 30 days provided integrity of the container is not comprised.

Code	Configuration Description	Dimension Description (inches)	Quantity
47413	Low/Small Size Tray only	(4 3/4 x 9 13/16 x 2 1/2)	12
47414	Low/Mid Size Tray only	(9 7/16 x 9 13/16 x 2 1/2)	12
47914	Low/Small Size Lid & Tray	(5 3/4 x 10 1/8 x 2 7/8)	1
47915	Low/Full Size Lid & Tray	(19 11/64 x 10 1/8 x 2 7/8)	1
47916	High/Full Size Lid & Tray	(19 11/64 x 10 1/8 x 4 3/8)	1
47416	Low/Full Size Tray only	(18 7/8 x 9 13/16 x 2 1/2)	6
47917	Low/Small Size Lid & Tray	(5 3/64 x 12 3/12 x 2 7/8)	1
47417	High/Mid Size Tray only	(9 7/16 x 9 13/16 x 3 15/16)	6
47918	Low/Mid Size Lid & Tray	(9 49/64 x 12 3/12 x 2 7/8)	1
47418	High/Full Size Tray only	(18 7/8 x 9 13/16 x 3 15/16)	6
47919	Low/Full Size Lid & Tray	(19 11/64 x 12 3/12 x 2 7/8)	1
47419	Low/Small Size Tray only	(4 3/4 x 11 13/16 x 2 1/2)	12
47920	Low/Mid Size Lid & Tray	(9 49/64 x 10 1/8 x 2 7/8)	1
47921	High/Mid Size Lid & Tray	(9 49/64 x 10 1/8 x 4 3/8)	1
47922	Low/Large Size Lid & Tray	(14 31/64 x 10 1/8 x 2 7/8)	1
47426	Low/Full Size Tray only	(18 7/8 x 11 13/16 x 2 1/2)	6
47425	Low/Mid Size Tray only	(9 7/16 x 11 13/16 x 2 1/2)	12
47428	Small Size Lid	(4 3/4 x 9 13/16 x 13/16)	6
47429	Full Size Lid	(18 7/8 x 9 13/16 x 13/16)	6
47430	Small Size Lid	(4 3/4 x 11 13/16 x 13/16)	6
47431	Mid Size Lid	(9 7/16 x 11 13/16 x 13/16)	6
47432	Full Size Lid	(18 7/8 x 11 13/16 x 13/16)	6
47442	Mid Size Lid	(9 7/16 x 9 13/16 x 13/16)	6

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.

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K203177

510(k) Summary - Sterisystem Dry-Base Instrument Tray

In accordance with 21 CFR 807.92, the following 510(k) summary is provided:

Date Summary was Prepared November 5, 2021

510(k) Submitter:
O & M Halyard, Inc.
1 Edison Drive
Alpharetta, GA 30005

Primary Contact for this 510(k) Submission:
Steven Dowdley, RAC
Tel: 678-451-8062
Email: steven.dowdley@hyh.com

Device Trade Name: Sterisystem Dry-Base Instrument Tray

Device Common Name: Sterilization Tray

Device Product Code and Classification Name:
KCT
Class II, 21 CFR §880.6850

Predicate Device: Smith & Nephew Multi Purpose Instrument Tray (K102122)

Subject Device Description:
The Sterisystem Dry-Base Instrument Trays are reusable sterilization trays. The trays are not intended to maintain sterility by themselves. Prior to sterilization, the trays must be wrapped with an appropriate FDA-cleared sterilization wrap to provide a microbial barrier which allows sterilant to permeate throughout the interior of the loaded tray.

The tray configurations are all trays and lids, available in various sizes. All trays are constructed of stainless steel metal meshbase and the lid are constructed of stainless steel and silicone. The tray and lid designs have a higher percentage of open cells than metal mesh allowing for complete permeation of sterilant. The trays have latches designed to fasten the lid onto the base.

Indications for Use:
The Sterisystem Dry-Base Instrument Tray are intended to protect medical device instrumentation and facilitate the sterilization process by sterilant penetration and air removal. When used in conjunction with an FDA cleared sterilization wrap, sterility of the enclosed medical device is maintained until used.

The system has been validated for the use in the following sterilization cycle:

Pre-Vacuum Steam	
Temperature	132°C (270°F)
Sterilization Time	4 minutes
Drying time	30
Maximum Tray Weight	Up to 25lbs depending on the weight limit of the cleared sterilization wrap used.

Pre-Vacuum sterilized devices may be stored in a protective storage for up to 30 days provided integrity of the container is not comprised.

Technological Characteristics

Shown below is a comparison of the technological and performance characteristics of the subject and predicate device.

	Subject Device	**Predicate Device K102122**	**Comparison**
FDA Product Code:	KCT	KCT	Same
FDA Classification:	Class II	Class II	Same
Regulation Number:	880.6250	880.6250	Same
Common Name:	Sterilization Tray	Sterilization Tray	Same
Intended Use	The Sterisystem Dry-Base Instrument Tray are intended to protect medical device instrumentation and facilitate the sterilization process by sterilant penetration and air removal. When used in conjunction with an FDA cleared sterilization wrap, sterility of the enclosed medical device is maintained until used. The system has been validated for the use in the following pre-vacuum steam sterilization cycle: Pre-Vacuum Steam Temperature 132ºC (270ºF) Sterilization Time 4 minutes Drying time 30 minutes Maximum Weight 25lbs Pre-Vacuum sterilized devices may be stored in a protective storage for up to 30 days provided integrity of the container is not comprised. The maximum weight load is 25lbs. (See IFU for table of part numbers & contents)	Smith & Nephew Multi-Purpose Sterilization trays are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The subject instrument trays are suitable for use in a prevacuum steam sterilization method. The subject instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with an FDA cleared sterilization wrap in order to maintain sterility of the enclosed devices Method: Pre-vacuum steam Temp: 132 – 135C Exposure 4 minutes Drying Time: 30 minutes	Same
Models	47413 Low/Small Size Tray only (4 3/4 x 9 13/16 x 2 1/2) 47414 Low/Mid Size Tray only (9 7/16 x 9 13/16 x 2 1/2) 47914 Low/Small Size Lid & Tray (5 3/4 x 10 1/8 x 2 7/8) 47915 Low/Full Size Lid & Tray (19 11/64 x 10 1/8 x 2 7/8)	Not listed	Different

	47916 High/Full Size Lid & Tray (19 11/64 x 10 1/8 x 4 3/8) 47416 Low/Full Size Tray only (18 7/8 x 9 13/16 x 2 1/2) 47917 Low/Small Size Lid & Tray (5 3/64 x 12 3/12 x 2 7/8) 47417 High/Mid Size Tray only (9 7/16 x 9 13/16 x 3 15/16) 47918 Low/Mid Size Lid & Tray (9 49/64 x 12 3/12 x 2 7/8) 47418 High/Full Size Tray only (18 7/8 x 9 13/16 x 3 15/16) 47919 Low/Full Size Lid & Tray (19 11/64 x 12 3/12 x 2 7/8) 47419 Low/Small Size Tray only (4 3/4 x 11 13/16 x 2 1/2) 47920 Low/Mid Size Lid & Tray (9 49/64 x 10 1/8 x 2 7/8) 47921 High/Mid Size Lid & Tray (9 49/64 x 10 1/8 x 4 3/8) 47922 Low/Large Size Lid & Tray (14 31/64 x 10 1/8 x 2 7/8) 47426 Low/Full Size Tray only (18 7/8 x 11 13/16 x 2 1/2) 47425 Low/Mid Size Tray only (9 7/16 x 11 13/16 x 2 1/2) 47428 Small Size Lid (4 3/4 x 9 13/16 x 13/16) 47429 Full Size Lid (18 7/8 x 9 13/16 x 13/16) 47430 Small Size Lid (4 3/4 x 11 13/16 x 13/16) 47431 Mid Size Lid (9 7/16 x 11 13/16 x 13/16) 47432 Full Size Lid (18 7/8 x 11 13/16 x 13/16) 47442 Mid Size Lid (9 7/16 x 9 13/16 x 13/16)		
Composition:	Stainless steel, Silicone	Stainless steel/ Silicone	Same
			Similar

Reuse	Reusable device	Reusable device	Same
Sterilization:	Steam Sterilization	Steam Sterilization	Same
Material of construction	Stainless Steel and silicone	Stainless Steel and silicone	Same
Design:	Perforated design	Perforated design	Same
Re-useable:	Reusable	Reusable	Same
Drying time:	30 minutes	30 minutes	Same

Non-Clinical Performance Testing:

Sterilization Effectiveness
Sterilization validations were performed to verify the effectiveness of steam sterilization of the Sterisystem Dry-Base Instrument Tray using a pre-vacuum cycle. The study evaluated the resistance of biological indicators (BIs) with 10^6 Geobacillus stearothermophilus spores to 132°C pre-vacuum steam autoclave half cycle exposures.

For each sterilization wrap and tray tested:

- All biological indicator test samples were negative for growth following the incubation period.
- The positive controls were positive for growth.
- The negative and environmental controls were negative for growth.
- The integrators demonstrated steam penetration.

Dry time was also evaluated after sterilization and determined to be 30 minutes.

30 Day Storage
The subject device is not intended to maintain sterility. The sterilization tray is intended to be used in conjunction with an FDA cleared sterilization wrap in order to maintain sterility of the enclosed device. Maintenance of sterility was however evaluated on the subject device with a cleared sterilization for 30 days.

Cleaning Validation
A manual and automated cleaning validation was performed to validate the cleaning instructions. The results indicate that the recommended cleaning methods were effective in removing soil from all designated surfaces of the of the subject device.

Biocompatibility
Biocompatibility testing was conducted on all materials used in construction of the subject device per ISO 10993. Test article extracts showed grade 2 or less cell lysis and reactivity, indicating the materials met acceptable cytotoxicity levels.

Life Cycle Testing
Life cycle testing was performed to verify that the device maintained functional quality requirements, material integrity, and traceability after exposure to repeated pre-vacuum steam sterilization cycles, automated washing cycles and simulated functional use of the components. All results of performance testing met acceptance criteria

Conclusion
The conclusions drawn from the nonclinical tests demonstrate that the Sterisystem Dry-Base Instrument Tray is as safe, as effective and perform as well as or better than the legally marketed predicate device cleared under K102122