December 1, 2020

STERIS Corporation
Jennifer Nalepka
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K203199
Trade/Device Name: RAS 12 Rack / RAS 12 Long Rack, used in RAS Cycle of AMSCO 7052HP / 7053HP Single Chamber Washer-Disinfector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NVE
Dated: October 28, 2020
Received: October 29, 2020

Dear Jennifer Nalepka:

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,

For CAPT Elizabeth Claverie-Williams, MS
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)*
K203199

Device Name
RAS 12 Rack / RAS 12 Long Rack, used in RAS Cycle of AMSCO 7052HP / 7053HP Single Chamber Washer-Disinfector

Indications for Use *(Describe)*

The RAS Racks are used in the RAS Cycle of the AMSCO 7052HP Single-Chamber Washer/Disinfector and the AMSCO 7053HP Single-Chamber Washer/Disinfector for the effective cleaning, rinsing, intermediate level disinfection and drying of reusable da Vinci® X/Xi and S/Si EndoWrist® instruments.

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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510(k) Summary
For
RAS Racks and RAS Cycle in
AMSCO® 7052HP / 7053HP
Single Chamber Washer/Disinfectors

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Submission Date: November 16, 2020

Premarket Notification Number: K203199

1. Device Name

Trade Name:	**RAS 12 Rack / RAS 12 Long Rack, used in RAS Cycle of AMSCO 7052HP / 7053HP Single Chamber Washer-Disinfector**
	Class II
Device Class:	Endoscope cleaning accessory
Common/usual Name:	Endoscope washer, cleaner, automated
Classification Name:	21 CFR 876.1500
Classification Number:	NVE
Product Code:	

2. Predicate Device

RAS 12 Rack, RAS 12 Long Rack, RAS Cycle of the AMSCO 7052HP and 7053HP Single Chamber Washer Disinfector, K200577

3. Device Description

The RAS Racks are designed to enable the mechanical cleaning, rinsing, and disinfection of up to twelve (12) robotic-assisted surgery instruments in a compatible washer-disinfector. Twelve soiled da Vinci X/Xi and S/Si Endowrist® instruments, with limited prior manual pre-cleaning, are loaded into the appropriate RAS Rack according to the provided instructions for use. The rack is placed in the AMSCO 7052HP or 7053HP Single-Chamber Washer/Disinfector, and the RAS Cycle is selected.

The RAS Cycle performs automated cleaning through a validated series of spray-washing, lumen flushing steps that use Prolystica Ultra Concentrate HP Enzymatic Cleaner alternately with Prolystica Ultra Concentrate HP Neutral Detergent in temperature-controlled solutions. When the series of automated prewash and washing stages are complete, a one-minute rinse occurs. Next the RAS Cycle completes a thermal rinse to achieve intermediate level disinfection of the load before drying it. Upon RAS Cycle completion, the devices are ready to be prepared and packed for steam sterilization.

4. Indications for Use

The RAS Racks are used in the RAS Cycle of the AMSCO 7052HP Single-Chamber Washer/Disinfector and the AMSCO 7053HP Single-Chamber Washer/Disinfector for the effective cleaning, rinsing, intermediate level

disinfection and drying of reusable da Vinci® X/Xi and S/Si EndoWrist® instruments.

5. Technological Characteristics Comparison Table

A comparison of technical characteristics between the proposed and predicate devices is summarized in **Table 1**.

Table 1. Technological Characteristics Comparison Table

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K200577)	Comparison
Intended Use **Indications for Use**	The RAS Racks are used in the RAS Cycle of the AMSCO 7052HP Single-Chamber Washer/Disinfector and the AMSCO 7053HP Single-Chamber Washer/Disinfector for the effective cleaning, rinsing, intermediate level disinfection and drying of reusable da Vinci® X/Xi and S/Si EndoWrist® instruments.	The RAS Racks are used in the RAS Cycles of the AMSCO 7052HP and 7053HP Single-Chamber Washer/Disinfectors for the effective cleaning, rinsing, drying and intermediate level disinfection of reusable da Vinci EndoWrist® X/Xi, S/Si, and Single-Site instruments and staplers.	Identical except for removal of Single-Site and Stapler instruments and re-ordering of wording to more accurately identify the intended da Vinci devices.
Operating Principles / Technology	The RAS Racks and RAS Cycle of the 7052HP/7053HP SC w/d provide the necessary combination of cleaning agents in hot water with temperature and water pressure control during timed sequences to achieve effective cleaning of complex lumened da Vinci instruments. Validated parameters of the RAS cycle, which includes prewash, cleaning stages, rinsing, intermediate level thermal disinfection, and heated drying, cannot be reduced from the minimum default parameters.	The RAS Racks and RAS Cycle of the 7052HP/7053HP SC w/d provide the necessary combination of cleaning agents in hot water with temperature and water pressure control during timed sequences to achieve effective cleaning of complex lumened da Vinci instruments and staplers. Validated parameters of the RAS cycle, which includes prewash, cleaning stages, rinsing, intermediate level thermal disinfection, and heated drying, cannot be reduced from the minimum default parameters.	Identical except for the removal of Single-Site and Stapler instruments.

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K200577)	Comparison
Where Used	Hospital/medical center SPD	Hospital/medical center SPD	Identical
Design	The Washer/Disinfector is a stand-alone pass-through design single-chamber unit with integrated software. The RAS Racks position and provide flow to loaded da Vinci items throughout the RAS Cycle while spray arms assure all surfaces are cleaned with validated chemistries, rinsed, thermal disinfected, and dried.	The Washer/Disinfector is a stand-alone pass-through design single-chamber unit with integrated software. The RAS Racks position and provide flow to loaded da Vinci items throughout the RAS Cycle while spray arms assure all surfaces are cleaned with validated chemistries, rinsed, thermal disinfected, and dried.	Identical
Instrument preparation	Reusable EndoWrist® X/Xi, S/Si instruments are handled at point of use in the OR, then transferred to the Decontamination Area of the sterile processing department where they are prepared for automated cleaning and installed in the appropriate RAS Rack according to the detailed instructions provided in its Operator Manual.	Reusable EndoWrist® X/Xi, S/Si, and Single-Site instruments and staplers are handled at point of use in the OR, then transferred to the Decontamination Area of the sterile processing department where they are prepared for automated cleaning per the da Vinci Addendum for Automated Reprocessing Manual) and installed in the appropriate RAS Rack according to the detailed instructions provided in its Operator Manual.	Similar; removed Single-Site and Stapler instrument processing instructions. Incorporated the manual pre-cleaning steps from da Vinci Addendum Automated Reprocessing Manual.
Critical Parameters for Cleaning	Minimum critical cycle parameters are provided by default in the RAS Cycle: • Dosing of validated concentrated chemistries at specified volume of 0.74 oz. (22 mL) • Series of washing stages: ➢ 2-minute Prewash, not heated ➢ Wash phase 1 - initial 6-minute stage @122°F with Prolystica Ultra Concentrate HP	Minimum critical cycle parameters are provided by default in the RAS Cycle: • Dosing of validated concentrated chemistries at specified volume of 0.74 oz. (22 mL) • Series of washing stages: ➢ 2-minute Prewash, not heated ➢ Wash phase 1 - initial 6-minute stage @122°F with Prolystica Ultra Concentrate HP	Identical

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K200577)	Comparison
	Enzymatic Cleaner followed by 6-minute stage @150°F with Prolystica Ultra Concentrate HP Detergent ➢ 2-minute rinse, not heated ➢ Wash phases 3 and 4, each - initial 6-minute stage @122°F with Prolystica Ultra Concentrate HP Enzymatic Cleaner followed by 6-minute stage @150°F with Prolystica Ultra Concentrate HP Detergent ➢ 1-minute rinse, not heated • Pump provides continuous circulation through lumens and spray arms at pressure above 45 psi	Enzymatic Cleaner followed by 6-minute stage @150°F with Prolystica Ultra Concentrate HP Detergent ➢ 2-minute rinse, not heated ➢ Wash phases 3 and 4, each - initial 6-minute stage @122°F with Prolystica Ultra Concentrate HP Enzymatic Cleaner followed by 6-minute stage @150°F with Prolystica Ultra Concentrate HP Detergent ➢ 1-minute rinse, not heated • Pump provides continuous circulation through lumens and spray arms at pressure above 45 psi	
Critical Parameters for Thermal Disinfection	Minimum critical cycle parameters are provided by default in the RAS Cycle: • Temperature 194°F (90°C) • Time 1 minute • A_0 = 600	Minimum critical cycle parameters are provided by default in the RAS Cycle: • Temperature 194°F (90°C) • Time 1 minute • A_0 = 600	Identical
Drying	• Temperature (high = setpoint 220°F) • Default time 20 minutes (adjustable from 2 to 30 minutes)	• Temperature (high = setpoint 220°F) • Default time 20 minutes (adjustable from 2 to 30 minutes)	Identical
Record keeping	Provides printout or download capability from USB port or using optional printer	Provides printout or download capability from USB port or using optional printer	Identical
Water Quality	< 120 ppm hardness	< 120 ppm hardness	Identical

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K200577)	Comparison
Sonication	No capability	No capability	Identical
Process Monitors:	• Monitors water temperature for each filling of the sump • Monitors time of each phase at set point temperature. • Monitors water fill volume • Monitors volume of cleaner injected • Monitors pump rotation	• Monitors water temperature for each filling of the sump • Monitors time of each phase at set point temperature. • Monitors water fill volume • Monitors volume of cleaner injected • Monitors pump rotation	Identical
Cleaner dispensed	Washer/disinfector automatically dispenses the validated volume of concentrated chemistry at specified points in the RAS Cycle.	Washer/disinfector automatically dispenses the validated volume of concentrated chemistry at specified points in the RAS Cycle.	Identical
Cleaning chemistries	Uses only Prolystica Ultra Concentrate HP Enzymatic Cleaner and Prolystica Ultra Concentrate HP Neutral Detergent in RAS Cycle.	Uses only Prolystica Ultra Concentrate HP Enzymatic Cleaner and Prolystica Ultra Concentrate HP Neutral Detergent in RAS Cycle.	Identical
Cycle time	Approximately 1 hour and 15 - 20 minutes	Approximately 1 hour and 15 - 20 minutes	Identical
# Instruments	Up to 12 da Vinci instruments/cycle	Up to 12 da Vinci instruments and/or staplers/cycle	Identical except for the removal of Single-Site and Stapler instruments
Self-Disinfection Cycle	• No self-disinfection cycle. • A Decon Cycle using AMSCO Liquid Descaler is run once weekly.	• No self-disinfection cycle. • A Decon Cycle using AMSCO Liquid Descaler is run once weekly.	Identical
Filters	Each RAS Rack features an in-line, self-cleaning filtration assembly. Operator performs	Each RAS Rack features an in-line, self-cleaning filtration assembly. Operator performs	Identical

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K200577)	Comparison
	a manual cleaning step weekly.	a manual cleaning step weekly.	
Accessories	Prolystica Ultra Concentrate HP Enzymatic Cleaner and Prolystica Ultra Concentrate HP Neutral Detergent	Prolystica Ultra Concentrate HP Enzymatic Cleaner and Prolystica Ultra Concentrate HP Neutral Detergent	Identical

6. Summary of Non-Clinical Performance Testing

The purpose of this Special 510(k) is to update labeling consistent with a labeling revision being enacted by Intuitive Surgical to allow for automated cleaning and intermediate level disinfection of reusable da Vinci X/Xi and S/Si EndoWrist® instruments in the RAS Racks and RAS Cycles of the AMSCO 7052HP and 7053HP Single-Chamber Washer/Disinfectors. The RAS Racks and associated RAS Cycles were not altered in anyway.

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well or better than the legally marketed predicate device (K200577), Class II (21 CFR 876.1500), product code NVE.