



August 21, 2019

STERIS Corporation
Marcia Benedict
Senior Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K190081

Trade/Device Name: RAS-12 Rack, RAS 12 Long Rack; 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: July 19, 2019

Received: July 22, 2019

Dear Marcia Benedict:

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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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

Indications for Use

510(k) Number (*known*)

K190081

Device Name

RAS 12 Rack / RAS 12 Long Rack, used in RAS Cycle of AMSCO^(R) 7052HP / 7053HP Single Chamber Washer-Disinfector

Indications for Use (Describe)

The RAS Racks are used in the RAS Cycles of 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.

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 12 Rack, Ras 12 Long Rack and
RAS Cycle in AMSCO® 7052HP /
7053HP
Single Chamber Washer-Disinfectors**

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Submission Date: July 19, 2019

Premarket Notification Number: K190081

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

1. Device Name

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

2. Predicate Device

da Vinci SonicPro Cleaning System: K073112

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 Endowrist X/Xi, S/Si, or Single-Site instruments and staplers, without prior manual cleaning, are loaded into the appropriate RAS Rack according to the provided instructions for use. The rack is placed in the AMSCO 7052HP or 7053L 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 Cycles of 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.

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 K190081 RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device da Vinci SonicPro Cleaning System (K073112)	Comparison
Intended Use Indications for Use	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.	The da Vinci SonicPro Cleaning System is intended for the automated cleaning of reusable <i>EndoWrist</i> Instruments and accessories used with the da Vinci and da Vinci S surgical systems. The Cleaning System when used in accordance with its labeling provides an automated cleaning method as part of the re-processing sequence for the <i>EndoWrist</i> Instruments and Accessories.	The intended use is the same; details provided differ. The proposed device specifically names claimed da Vinci <i>EndoWrist</i> device models. The proposed device achieves cleaning without preliminary manual cleaning, while the predicate device requires EndoWrist manual cleaning.
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 and staplers. Validated parameters of the RAS cycle, which includes prewash, cleaning stages, rinsing, intermediate	The Cleaning System provides a microprocessor controlled unit with the ability to clean internal and external surfaces of lumened robotic surgical instruments such as the da Vinci EndoWrist instruments. Cleaning follows manual cleaning steps and is accomplished through use of hot water, user-selected detergent, flow, ultrasonic energy, and rinsing	Similar; however The predicate includes use of ultrasonic energy The proposed device includes thermal disinfection and drying, without sonication.

Feature	Proposed Device K190081 RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device da Vinci SonicPro Cleaning System (K073112)	Comparison
	level thermal disinfection, and heated drying, cannot be reduced from the minimum default parameters.	mechanism.	
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 Cleaning System is a stand-alone unit mounted on a movable frame with integrated hardware and software. Provides temperature controlled spray, ultrasonic cleaning, and flushing with user-selected chemistries. Includes pumps, filter, chamber/tank, basket, flush tubes, printer connection.	Similar
Instrument preparation	Reusable EndoWrist X/Xi, S/Si, and Single-Site instruments and staplers are handled at point of use in the OR per the manufacturer's IFU (da Vinci Instrument Reprocessing Manual). When received in the SPD within one hour they are flushed with water and installed in the appropriate RAS Rack according to the detailed instructions provided in its Operator Manual.	Thoroughly clean the outside of the entire instrument or accessory using running water with a clean, soft, nylon bristled brush. Repeat scrubbing as needed. See Reprocessing Instructions PN 550875. Thoroughly rinse. Place in SonicPro instrument basket. Attach the slip luer end of flush tubes to main flush port of each instrument and to quick-connect fittings in tank.	Different instrument prep required, as reflected in intended use statements.
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	The critical process parameters are: Instrument Cycle (5mm or 8 mm): • 30 – 45 °C (86 - 113°F) • User-selected pH neutral cleaning agent @ 0.5 oz/gal – 3.0 oz/gal	Each system has established critical parameters to achieve validated outcomes. The cycles differ.

Feature	Proposed Device K190081 RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device da Vinci SonicPro Cleaning System (K073112)	Comparison
	heated ➤ Wash phase 1 - 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 ➤ 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	• 135 W/gal ultrasonic power density • 30 psi minimum flushing pressure Accessory Cycle: • 25 – 45 °C (77 - 113°F) • User-selected pH neutral cleaning agent @ 0.5 oz/gal – 3.0 oz/gal • 135 W/gal ultrasonic power density • 30 psi minimum flushing pressure	
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	No disinfection cycle	Capabilities differ
Drying	• Temperature (high = setpoint 220°F) • Default time 20 minutes (adjustable from 2 to 30 minutes)	No drying capability	Capabilities differ
Record keeping	Provides printout or download capability from USB port or using optional printer	Connection to separate thermal printer	Capabilities differ
Water Quality	< 120 ppm hardness	< 200 ppm hardness	Similar

Feature	Proposed Device K190081 RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device da Vinci SonicPro Cleaning System (K073112)	Comparison
Sonication	No capability	135 W/gal ultrasonic power density	Capabilities differ
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 tank - Monitors pressure to ensure it remains above 30 psi - Monitors power drawn by ultrasonics - Senses flow of cleaning solution at proper pressure for dose	Each system provides monitoring suitable to assure critical parameters are met.
Cleaner dispensed	Washer/disinfector automatically dispenses the validated volume of concentrated chemistry at specified points in the RAS Cycle.	Cleaning System injects user-selected cleaning solution at user-selected volume between 0.5 oz/gal – 3.0 oz/gal (in increments of 0.5 oz.)	Similar; predicate allows volume to be altered
Cleaning chemistries	Uses only Prolystica Ultra Concentrate HP Enzymatic Cleaner and Prolystica Ultra Concentrate HP Neutral Detergent in RAS Cycle.	Use only pH-neutral, low-foaming, enzymatic cleaning agents	Proposed device limits options to validated cleaners; predicate cleaner is user-selected
Cycle time	Approximately 1 hour and 15 - 20 minutes	Approximately 40 minutes Instrument Cycles, 30 minutes Accessory Cycle	Predicate cycles are shorter
# Instruments	Up to 12 da Vinci instruments and/or staplers/cycle	Up to 10 instruments/cycle	Proposed device can process more
Self-Disinfection Cycle	No self-disinfection cycle. A Decon Cycle using AMSCO Liquid Descaler is run once weekly.	No self-disinfection cycle. System Purge Cycle (5 min. cleaning with hot water and ultrasonics followed by hot water and ultrasonic rinse) is performed daily.	Similar

Feature	Proposed Device K190081 RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device da Vinci SonicPro Cleaning System (K073112)	Comparison
Filters	Each RAS Rack features an in-line, self-cleaning filtration assembly. Operator performs a manual cleaning step weekly.	Includes a 10-micron water filter that is replaced annually or after 200 cycles, whichever comes first	Each provides filtration differently
Accessories	Prolystica Ultra Concentrate HP Enzymatic Cleaner and Prolystica Ultra Concentrate HP Neutral Detergent	Thermal printer, Accessory and Instrument Baskets, Flush Tubes, unspecified cleaning agent	Accessories differ

6. Summary of Non-Clinical Performance Testing

Testing was performed to evaluate performance and demonstrate substantial equivalence to the predicate as summarized in **Table 2**. The RAS Racks and RAS Cycle of the AMSCO 7052HP / 7053HP Single-Chamber Washer/Disinfectors met the established performance criteria.

Table 2. Performance Testing

Test	Acceptance Criteria	Result
Simulated Use Testing	Endowrist instruments identified as master devices for their most challenging features were soiled and allowed to dry for at least one hour. They were processed in triplicate trials using the RAS Cycle to the end of the initial rinse (prior to thermal rinse), then examined visually and sampled for quantitation of two soil markers: protein <6.4 µg/cm ² , TOC <12 µg/cm ² .	PASS
In-Use Testing	Clinically used Endowrist instruments were installed in the Rack according to its IFU, the rack was placed in the washer/disinfector, and the RAS Cycle was run to the end of initial rinse (prior to thermal rinse). Instruments were examined visually and sampled for quantitation of two soil markers: protein <6.4 µg/cm ² , TOC <12 µg/cm ² .	PASS
Rinsing Efficacy and Biocompatibility	Two EndoWrist instruments were processed three (3) consecutive times in full loads using double cleaner concentrations. Rinse water and device extracts were tested for cytotoxicity. Device extracts were analyzed to verify that the chemical residual level is not cytotoxic	PASS

Thermal Disinfection	Achieves greater than 6-log reduction of each organism in a mixed suspension of vegetative organisms, and greater than 3-log reduction of mycobacterium species	PASS
W/D Physical Performance	Chemical injection control operates within specifications Temperature control operates within specifications Pump maintains high speed performance as designed Drying is achieved by the RAS Cycle	PASS
Human Factors	Typical users were capable of following the written instructions for use to correctly configure and load the RAS Rack and to select the correct cycle of the washer/disinfector.	PASS
Electrical Safety Conformance	UL 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements, 3rd Edition UL 61010-2-040 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials, 2nd Edition IEC 61326-1:2012 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements • conformance to FCC Part 15	PASS
Software Validation	The software that controls the system was validated and determined to operate effectively and as designed.	PASS

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 as or better than the legally marketed predicate device (K073112).