August 25, 2022

Anthony Piotrkowski
Director, Regulatory Affairs
Steris Inc.
5960 Heisley Rd
Mentor, Ohio 44060

Re: K222543
Trade/Device Name: AMSCO 600 Steam Sterilizer, V-PRO maX 2 Low Temperature Sterilization System, V-PRO s2 Low Temperature Sterilization System, RAS 12 Rack, RAS 12 Long Rack, RAS Cycle of the AMSCO 7052HP and 7053HP Single Chamber Washer Disinfector
Regulation Number: 21 CFR 880.6880; 21 CFR 880.6860; 21 CFR 876.1500
Regulation Name: Steam Sterilizer; Ethylene Oxide Gas Sterilizer; Endoscope And Accessories
Regulatory Class: Class II
Product Code: FLE,PEC, MLR, NVE
Dated: August 19, 2022
Received: August 22, 2022

Dear Anthony Piotrkowski:

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, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222543

Device Name

AMSCO 600 Steam Sterilizer

Indications for Use *(Describe)*

The AMSCO 600 Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are equipped with the following factory-programmed cycles (Table 1):

Table 1. AMSCO 600 Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Maximum Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each and Fabric Packs. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	10 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each . *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack.
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. *Refer to Table 2 for recommended quantities.*
Prevac-IUSS	270°F (132°C)	4 minutes	1 minutes	Immediate use – single unwrapped tray
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. *Refer to Table 2 for recommended quantities.*
Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3.5 minutes	1 minute	Bowie-Dick Test Pack, DART
Leak Test	N/A	N/A	N/A	N/A

Table 2 AMSCO 600 Steam Sterilizer full load per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26” x 26” x 39”	9	12
26” x 26” x 51”	12	16
26” x 26” x 63”	15	20

The Automated Load and Unload System (ALUS) provides semi-automated loading and unloading from an AMSCO 600 steam sterilizer when a cycle is complete. Alternatively, the ALUS may also be used to provide automatic unloading only in combination with manual loading. The ALUS can start a cycle automatically when equipped with the optional bar code reader.

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)

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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)*
K222543

Device Name
V-PRO maX 2 Low Temperature Sterilization Systems

Indications for Use *(Describe)*
The V-PRO maX 2 Low Temperature Sterilization System using VAPROX HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle and Fast Non Lumen Cycle.

The Non Lumen Cycle can sterilize:
‡Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
‡ The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs (22.7 kg).

The Fast Non Lumen Cycle can sterilize:
*Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
* The validation studies were conducted using a validation load consisting of one pouched instrument tray for a total weight of 11 lbs (5 kg).

The Flexible Cycle can sterilize:
Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain either:
• A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length
• Or two lumens with:
  - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
  - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. †† The flexible endoscope may contain either:
• A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
• Or two lumens with:
  - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
  - And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length.
†† The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg).

The Lumen Cycle can sterilize:
†Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

- Single channeled devices with a stainless lumen that is ≥ 0.77 mm ID and ≤ 500 mm in length
- Single channeled devices with a stainless lumen that is ≥ 1.8 mm ID and ≤ 542 mm in length
- Dual channeled devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
- Triple channeled devices with stainless lumens that are either:
  ≥ 1.2 mm ID and ≤ 275 mm in length
  ≥ 1.8 mm ID and ≤ 310 mm in length
  or
  ≥ 2.8 mm ID and ≤ 317 mm in length

† Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs (8.9 kg).

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222543

Device Name
V-PRO® s2 Low Temperature Sterilization System

Indications for Use *(Describe)*
The V-PRO s2 Low Temperature Sterilization System using VAPROX® HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The pre-programmed sterilization cycles operate at low pressure and low temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

The V-PRO s2 Sterilizer Non Lumen Cycle can sterilize:‡
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
‡ The validation studies were conducted using a validation load consisting of one instrument tray for a total weight of 25 lbs (11.3 kg).

The V-PRO s2 Sterilizer Fast Cycle can sterilize:‡
Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

- Single or dual channeled devices with stainless steel lumens that are
  ≥ 0.77 mm (~1/32”) internal diameter (ID) and ≤ 410 mm (~16-9/64”) in length
  ≥ 1.8 mm (~5/64") ID x ≤ 542 mm (~21-5/16") in length
- Triple channeled devices with stainless steel lumens that are either:
  ≥ 1.2 mm (~3/64”) ID and ≤ 275 mm (~10-53/64”) in length
  ≥ 1.8 mm (~5/64”) ID and ≤ 310 mm (~12-13/64”) in length
  or
  ≥ 2.8 mm (~7/64”) ID and ≤ 317 mm (12-31/64”) in length

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
‡ Validation testing for all lumen sizes was conducted using a maximum of eight (8) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. Validation testing was conducted using a validation load consisting of one pouched instrument tray and two pouched devices outside of the tray with a total weight of 4.0 lbs (~1.8kg).

The V-PRO s2 Sterilizer Flexible Cycle can sterilize:@
One surgical flexible endoscope (such as those used in ENT, Urology and Surgical Care) or bronchoscope with light cord (if not integral to endoscope), mat, and additional load.

- The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length
- Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions
  ≥ 0.76 mm (~1/32”) ID and ≤ 233 mm (~9 11/64”) in length
  ≥ 1.0 mm (~3/64”) ID and ≤ 254 mm (~10”) in length
  ≥ 1.8 mm (~5/64”) ID and ≤ 542 mm (~21-5/16”) in length

@ The validation studies were conducted using a validation load consisting of two instrument trays. One tray contained one flexible endoscope, with silicone mat, instrument organizers and light cord (if not integral to scope), and the second

tray contained additional load and twelve (12) stainless steel lumens for a total load weight of 11 lbs (5 kg). Hospital loads should not exceed the maximum number of lumens validated by this testing.

The V-PRO s2 Sterilizer Lumen Cycle can sterilize: ^
Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

- Single or dual channeled devices with stainless steel lumens that are
  ≥ 0.77 mm (~1/32") ID and ≤ 410 mm (16-9/64") in length
  ≥ 1.8 mm (~5/64) ID x ≤ 542 mm (~21-5/16") in length
- Triple channeled devices with stainless steel lumens that are either:
  ≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-53/64") in length
  ≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length
  or
  ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

^ Validation testing for all lumen sizes was conducted using a maximum of twelve (12) stainless steel lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of one instrument tray and two pouches for a total weight of 11 lbs (5.0 kg).

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)

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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)*

K222543

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)

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510(k) Summary
For
AMSCO 600 Steam Sterilizer

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Tony Piotrkowski
Director, Regulatory Affairs

Telephone: (440) 392-7437
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e-mail: Tony_Piotrkowski@steris.com

Summary Date: August 24, 2022

Premarket Notification Number: K222543

1. Device Name

Trade Name:	AMSCO 600 Steam Sterilizer
Device Class:	Class II
Common/usual Name:	Steam Sterilizer
Classification Name:	Sterilizer, Steam
Classification Number:	21 CFR 880.6880
Product Code:	FLE, PEC

2. Predicate Device

K211500 AMSCO 600 Steam Sterilizer

3. Description of Device

The AMSCO 600 Steam Sterilizer uses saturated steam, generated from a house steam utility (e.g. boiler system) or from a steam generator, to sterilize heat-stable health care products.

The sterilizer accomplishes this by removing the air in the chamber, exposing the load to saturated steam for a defined combination of time and temperature, and drying the load. Removal of air from the chamber occurs using either of two methods, gravity displacement or mechanical vacuum. Once the air removal phase is completed, the sterilizer progresses to the steam exposure phase. During the steam exposure phase, every surface of the load is exposed to saturated steam for a defined combination of time and temperature. Once the steam exposure phase is completed, steam is removed from the chamber and the load is dried using the latent heat in the load and the vacuum pump.

The sterilizers are generally operated by technicians in a central service or sterile processing department of healthcare facilities. Sterilizers may also be located in a surgical suite to allow for Immediate Use Steam Sterilization (IUSS) for instances where an instrument is needed immediately for a procedure (e.g. after an instrument has been dropped and there is no replacement readily available). Standard practices for use of sterilizers in health care facilities are provided by various organizations (e.g. ANSI/AAMI ST79).

The ALUS is used with the AMSCO 600 Steam Sterilizer's existing transfer carriages and loading carts. It consists of a conveyor system which attaches to the load and/or unload ends of the steam sterilizer. It has a series of barcode labels which correspond to pre-programmed cycles and an optional scanner which when fitted to the system will communicate to the sterilizer which cycle to initiate.

4. Intended Use/Indications for Use

The AMSCO 600 Steam Sterilizers are designed for sterilization of heat and moisture- stable materials used in healthcare facilities and are equipped with the following factory- programmed cycles:

AMSCO 600 Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Maximum Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each and Fabric Packs. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	10 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack.
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. Refer to Table 2 for recommended quantities.
Prevac-IUSS	270°F (132°C)	4 minutes	1 minutes	Immediate use – single unwrapped tray
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. Refer to Table 2 for recommended quantities.
Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3.5 minutes	1 minute	Bowie-Dick Test Pack, DART
Leak Test	N/A	N/A	N/A	N/A

AMSCO 600 Steam Sterilizer full load per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26” x 26” x 39”	9	12
26” x 26” x 51”	12	16
26” x 26” x 63”	15	20

The Automated Load and Unload System (ALUS) provides semi-automated loading and unloading from an AMSCO 600 steam sterilizer when a cycle is complete. Alternatively, the ALUS may also be used to provide automatic unloading only in combination with manual loading. The ALUS can start a cycle automatically when equipped with the optional bar code reader.

Technological Characteristics Comparison Table

Feature	AMSCO 600 Steam Sterilizer (Modified Device)	AMSCO 600 Steam Sterilizer (Predicate Device/K211500)	Comparison
Intended Use	The AMSCO 600 Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities.	The AMSCO 600 Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities.	Same
Critical Process Parameters	• Time • Chamber Temperature • Pressure	• Time • Chamber Temperature • Pressure	Same
Control	Embedded Controller	Embedded Controller	Same control but using refurbished/slightly modified boards
SAL	10^{-6}	10^{-6}	Same
Sterilant	Saturated Steam	Saturated Steam	Same
Utilities	Steam, Water, Electricity, Air	Steam, Water, Electricity, Air	Same
Chamber Material	316L Stainless Steel	316L Stainless Steel	Same
Nominal Chamber Size	• 26” w x 26” h x 39” d • 26” w x 26” h x 51” d • 26” w x 26” h x 63” d	• 26” w x 26” h x 39” d • 26” w x 26” h x 51” d • 26” w x 26” h x 63” d	Same
Door	304L Stainless Steel 26” x 26” Power vertical sliding	304L Stainless Steel 26” x 26” Power vertical sliding	Same
Chamber Pressure Rating	45 psig, 300°F	45 psig, 300°F	Same
Door Seal	Steam activated door seal	Steam activated door seal	Same
External Process Monitors	• Electronic Control • Printer	• Electronic Control • Printer	Same
Accessories	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment, automated loading system	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment, automated loading system	Same
Test Cycles	Warm Up, Leak Test, DART (Bowie Dick) Test	Warm Up, Leak Test, DART (Bowie Dick) Test	Same
Internal Process Monitors	**Temperature** -Dual element RTD located in chamber drain - RTD located in the jacket drain - RTD located in heat exchanger **Pressure** -Pressure transducer in chamber	**Temperature** -Dual element RTD located in chamber drain - RTD located in the jacket drain - RTD located in heat exchanger **Pressure** -Pressure transducer in chamber	Same
Performance	Meets ANSI/AAMI ST8:2013	Meets ANSI/AAMI ST8:2013	Same
Cycles	• 270F, Prevac, 4’ Full fabric pack • 270F, Prevac, 4’ Full tray • 270F, Prevac, 4’ One fabric pack • 270F, Prevac, 4’ IUSS • 275F, Prevac, 3’ Full fabric • 250F, Gravity, 30’ Full tray • 270F, Prevac, 10’ Full tray	• 270F, Prevac, 4’ Full fabric pack • 270F, Prevac, 4’ Full tray • 270F, Prevac, 4’ One fabric pack • 270F, Prevac, 4’ IUSS • 275F, Prevac, 3’ Full fabric • 250F, Gravity, 30’ Full tray • 270F, Prevac, 10’ Full tray	Same
Full Loads	• 39”: 9, 25-lb double wrapped trays or 12, fabric packs • 51”: 12, 25-lb double wrapped trays or 16, fabric packs • 63”: 15, 25-lb double wrapped trays or 20, fabric packs	• 39”: 9, 25-lb double wrapped trays or 12, fabric packs • 51”: 12, 25-lb double wrapped trays or 16, fabric packs • 63”: 15, 25-lb double wrapped trays or 20, fabric packs	Same

The proposed device has the same intended use as the predicate with the same technological characteristics. The modifications, subject of this submission, are to use refurbished control boards and control boards that have been slightly modified by using alternative, drop-in replacement components in the manufacture of the devices. Note that refurbishing for the purposes of the process covered by this submission consists of clearing the memory and uploading the most recent software.

5. Summary of Nonclinical Tests

The AMSCO 600 Steam Sterilizer has the same intended use and technological characteristics that do not raise different questions of safety and effectiveness as compared to the predicate device. Testing to assess and demonstrate substantial equivalence to the predicate is summarized below.

Test	Criterion	Conclusion
½ Cycle sterility assurance Test	All biological indicators must show no growth after a ½ Cycle exposure with a worst-case load.	Pass
Software confirmation test	Ensure proper version, proper operation of cycles and alarms	Pass

6. Conclusion

Based on the intended uses, 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 K211500, Class II (21 CFR 880.6860), product code FLE and the use of refurbished/ slightly modified boards has no impact on the device performance.

510(k) Summary For
V-PRO® maX 2 Low Temperature Sterilization System

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Fax No: (440) 357-9198

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Submission Date: August 24, 2022

Premarket Notification Number: K222543

1. Device Name

Trade Name:	V-PRO® maX 2 Low Temperature Sterilization System
Device Class:	Class II
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
Classification Number:	21 CFR 880.6860
Product Code:	MLR

2. Predicate Device

K190103, V-PRO maX and maX 2 V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems.

3. Description of Device

The V-PRO Low Temperature Sterilization System is a vaporized hydrogen peroxide sterilizer. It has the following pre-programmed cycles (the Lumen Cycle, the Non Lumen Cycle, the Flexible Cycle and the Fast Non Lumen Cycle). The V-PRO Low Temperature Sterilization System is intended for terminal sterilization of cleaned, rinsed, dried and packaged reusable surgical instruments used in healthcare facilities.

The V-PRO Sterilizers uses VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). The four pre-programmed cycles all use a conditioning phase, a sterilize phase and an aeration phase. Packaged sterilized devices are ready for use at the completion of the cycle, no cool down or aeration period is required following completion of the cycle.

4. Intended Use / Indications for Use

The maX 2 Low Temperature Sterilization System using VAPROX HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle and the Fast Non Lumen Cycle.

The Non Lumen Cycle can sterilize: ‡

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

‡ The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs (22.7 kg).

The Fast Non Lumen Cycle can sterilize:*

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

** The validation studies were conducted using a validation load consisting of one pouched instrument tray for a total weight of 11 lbs (5 kg).*

The Flexible Cycle can sterilize:

Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain either:
• A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length
• Or two lumens with:
▪ One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
▪ And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

** The validation studies were conducted with two flexible endoscopes, each packaged* into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. †† The flexible endoscope may contain either:
• A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
• Or two lumens with:
▪ One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
▪ And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length.

†† The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg).

The Lumen Cycle can sterilize: †

Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
• Single channeled devices with a stainless lumen that is ≥ 0.77 mm ID and ≤ 500 mm in length
• Single channeled devices with a stainless lumen that is ≥ 1.8 mm ID and ≤ 542 mm in length
• Dual channeled devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
• Triple channeled devices with stainless lumens that are either:
≥ 1.2 mm ID and ≤ 275 mm in length
≥ 1.8 mm ID and ≤ 310 mm in length
or
≥ 2.8 mm ID and ≤ 317 mm in length

† Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs (8.9 kg).

5. Technological Characteristics

The proposed and predicate devices are identical in all technological characteristics including but not limited to: fundamental scientific technology, composition, mechanism of action, components and accessories. No physical changes were made to the devices for this modification other than the chip modifications described herein.

Technological Characteristics Comparison Table

Feature	V-PRO maX 2Low Temperature Sterilization System (Proposed)	V-PRO1, 1-Plus, maX and maX 2 Low Temperature Sterilization System (Predicate – K190103)	Comparison
Intended Use	The maX 2 Low Temperature Sterilization System using VAPROX HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues	The maX 2 Low Temperature Sterilization System using VAPROX HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues	Same
Process Parameters	The critical process parameters are: • Time • Chamber Temperature • Vaporizer Temperature • Chamber Pressure Prior to Injection • Sterilant Injection Weight	The critical process parameters are: • Time • Chamber Temperature • Vaporizer Temperature • Chamber Pressure Prior to Injection Sterilant Injection Weight	Same
Software/ Firmware Controlled	Control system consists of a proprietary microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains user settings and calibration data indefinitely. Up to 300 cycle data files can be stored for review or downloading by the user. The software allows user selection of the pre- programmed cycle.	Control system consists of a proprietary microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains user settings and calibration data indefinitely. Up to 300 cycle data files can be stored for review or downloading by the user. The software allows user selection of the pre- programmed cycles.	Same control but using refurbished/slightly modified boards
Sterilant	VAPROX HC Sterilant (59% Hydrogen Peroxide).	VAPROX HC Sterilant (59% Hydrogen Peroxide).	Same
Accessories	Accessories were submitted under separate, individual, concurrent 510(k)s and cover the following: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape	Accessories were submitted under separate, individual, concurrent 510(k)s and cover the following: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape	Same

The proposed device has the same intended use as the predicate with the same technological characteristics. The modifications, subject of this submission, are to use refurbished and control boards that have been slightly modified by using alternative, drop-in replacement components in the manufacture of the devices.

Note that refurbishing for the purposes of the process covered by this submission consists of clearing the memory and uploading the most recent software and may also include replacement of minor components of the board.

6. Summary of Non-Clinical Testing

Non-clinical performance test was performed according to the test methodology listed below and is the same methods used to verify the original design. The testing demonstrated that the subject device met the acceptance criteria described in the standard/methodology.

Test	Criterion	Conclusion
½ Cycle sterility assurance Test	All biological indicators must show no growth after a ½ Cycle exposure with a worst-case load.	Pass
Software confirmation test	Ensure proper version, proper operation of cycles and alarms	Pass

7. Conclusions

Based on the intended use, technological characteristics and non-clinical performance data, the V-PRO maX 2 Low Temperature Sterilization System is as safe, as effective and performs as well as or better than the legally marketed predicate device K190103, Class II (21 CFR 880.6860), product code MLR and the use of refurbished/slightly modified boards has no impact on the device performance.

510(k) Summary For
V-PRO® s2 Low Temperature Sterilization System

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Submission Date: August 24, 2022

Premarket Notification Number: K222543

2. Device Name

Trade Name:	V-PRO® s2 Low Temperature Sterilization Systems
Device Class:	Class II
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
Classification Number:	21 CFR 880.6860
Product Code:	MLR

3. Predicate Device

Predicate: **K190917,** V-PRO® s2 and V-PRO 60 Low Temperature Sterilization Systems

The proposed device has the same intended use as the predicate with the same technological characteristics. The modifications, subject of this submission, are to use refurbished control boards and control boards that have been slightly modified by using alternative, drop-in replacement components in the manufacture of the devices. Note that refurbishing for the purposes of the process covered by this submission in the manufacture of the devices consists of clearing the memory and uploading the most recent software and may also include replacement of minor components of the board.

4. Description of Device

The V-PRO s2 Sterilizer executes four sterilization cycles (the Lumen, Non Lumen, Flexible Cycles and Fast Cycle). The V-PRO s2 Sterilizer contains a cabinetry modification and is free-standing.

The V-PRO s2 Low Temperature Sterilization System is intended for terminal sterilization of cleaned, rinsed, dried and packaged surgical instruments used in healthcare facilities and utilizes VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). The pre-programmed cycles all use a conditioning phase, a sterilize phase and an aeration phase. The packaged sterilized devices are ready for use at the completion of the cycle, no cool down or aeration period is required following completion of the cycle.

5. Intended Use / Indications for Use

The V-PRO s2 Low Temperature Sterilization System using VAPROX® HC Sterilant are intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and low temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

The Non Lumen Cycle can sterilize:‡

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

‡ The validation studies were conducted using a validation load consisting of one instrument tray for a total weight of 25 lbs (11.3 kg).

The Fast Cycle can sterilize:‡

Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

• Single or dual channeled devices with stainless steel lumens that are
≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (~16-9/64") in length
≥ 1.8 mm (~5/64") ID x ≤ 542 mm (~21-5/16") in length

• Triple channeled devices with stainless steel lumens that are either:
≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-53/64") in length
≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length
or
≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

‡ Validation testing for all lumen sizes was conducted using a maximum of eight (8) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. Validation testing was conducted using a validation load consisting of one pouched instrument tray and two pouched devices outside of the tray with a total weight of 4.0 lbs (~1.8kg).

The Flexible Cycle can sterilize:@

One surgical flexible endoscope (such as those used in ENT, Urology and Surgical Care) or bronchoscope with light cord (if not integral to endoscope), mat, and additional load.

• The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length

• Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions
≥ 0.76 mm (~1/32") ID and ≤ 233 mm (~9 11/64") in length
≥ 1.0 mm (~3/64") ID and ≤ 254 mm (~10") in length
≥ 1.8 mm (~5/64") ID and ≤ 542 mm (~21-5/16") in length

@ The validation studies were conducted using a validation load consisting of two instrument trays. One tray contained one flexible endoscope, with silicone mat, instrument organizers and light cord (if not integral to scope), and the second tray contained additional load and twelve (12) stainless steel lumens for a total load weight of 11 lbs (5 kg). Hospital loads should not exceed the maximum number of lumens validated by this testing.

The Lumen Cycle can sterilize: ^

Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

• Single or dual channeled devices with stainless steel lumens that are
≥ 0.77 mm (~1/32") ID and ≤ 410 mm (16-9/64") in length
≥ 1.8 mm (~5/64) ID x ≤ 542 mm (~21-5/16") in length

• Triple channeled devices with stainless steel lumens that are either:

≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-53/64") in length
≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length
or
≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length
^ *Validation testing for all lumen sizes was conducted using a maximum of twelve (12) stainless steel lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of one instrument tray and two pouches for a total weight of 11 lbs (5.0 kg).*

Technological Characteristics Comparison Table

Feature	V-PRO s2 Low Temperature Sterlization System (Modified Device)	V-PRO s2 Low Temperature Sterlization System (Predicate Device K190917)	Comparison
Indications for Use	See completed indications for use below. No changes are being proposed to the device's intended use or indications for use		Identical
Process Parameters	The critical process parameters are: • Time • Chamber Temperature • Vaporizer Temperature • Chamber Pressure Prior to Injection • Sterilant Injection Weight	The critical process parameters are: • Time • Chamber Temperature • Vaporizer Temperature • Chamber Pressure Prior to Injection • Sterilant Injection Weight	Identical
Software/ Firmware Controlled	Control system consists of a microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains cycle settings and current cycle information. The software allows user selection of either the Lumen, Non Lumen, Flexible or Fast pre-programmed cycle.	Control system consists of a microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains cycle settings and current cycle information. The software allows user selection of either the Lumen, Non Lumen, Flexible or Fast pre-programmed cycle.	Same control but using refurbished/ slightly modifed boards
Total Cycle Time	Lumen Cycle - 60 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 38 minutes Fast Cycle - 19 minutes	Lumen Cycle - 60 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 38 minutes Fast Cycle - 19 minutes	Identical
Sterilant	VAPROX HC Sterilant (59% Hydrogen Peroxide).	VAPROX HC Sterilant (59% Hydrogen Peroxide).	Identical
Accessories	Accessories include: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape	Accessories include: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape	Identical

6. Summary of Non-Clinical Testing

Non-clinical performance test was performed according to the test methodology listed below and is the same methods used to verify the original design. The testing demonstrated that the subject device met the acceptance criteria described in the standard/methodology.

Test	Criterion	Conclusion
½ Cycle sterility assurance Test	All biological indicators must show no growth after a ½ Cycle exposure with a worst-case load.	Pass
Software confirmation test	Ensure proper version, proper operation of cycles and alarms	Pass

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the V-PRO s2 Low Temperature Sterilization System is as safe, as effective and performs as well as or better than the legally marketed predicate device K190917, Class II (21 CFR 880.6860), product code MLR and the use of refurbished/slightly modified boards has no impact on the device performance.

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

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Submission Date: August 24, 2022

Premarket Notification Number: K222543

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

RAS 12 Rack, RAS 12 Long Rack, RAS Cycle of the AMSCO 7052HP and 7053HP Single Chamber Washer Disinfector, K203199.

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 below.

Technological Characteristics Comparison Table

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Comparison
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 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.	Identical
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. 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
Control	Embedded Controller	Embedded Controller	Same control but using refurbished/ slightly modified boards
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 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.	Identical

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Comparison
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 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	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 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	Identical
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
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

Feature	Proposed Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors	Predicate Device RAS Racks and Cycles in AMSCO® 7052HP/7053HP Single-Chamber Washer/Disinfectors (K203199)	Comparison
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
Number of Instruments	Up to 12 da Vinci instruments/cycle	Up to 12 da Vinci instruments/cycle	Identical
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 a manual cleaning step weekly.	Each RAS Rack features an in-line, self-cleaning filtration assembly. Operator performs a manual cleaning step weekly.	Identical
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

The proposed device has the same intended use as the predicate with the same technological characteristics. The modifications, subject of this submission, are to use refurbished control boards and control boards that have been slightly modified by using alternative, drop-in replacement components in the manufacture of the devices. Note that refurbishing for the purposes of the process covered by this submission consists of clearing the memory and uploading the most recent software and may also include replacement of minor components of the board.

6. Summary of Non-Clinical Performance Testing

Non-clinical performance test was performed according to the test methodology listed below and is the same methods used to verify the original design. The testing demonstrated that the subject device met the acceptance criteria described in the standard/methodology.

Test	Criterion	Conclusion
Critical parameters test	Compare the cycle data of RAS cycle between refurbished and new Kodiak controllers to confirm the cleaning efficiency	Pass
Software confirmation test	Ensure proper version, proper parameters are in the cycles for proper operation of cycles	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 (K203199), Class II (21 CFR 876.1500), product code NVE and the use of refurbished/slightly modified boards has no impact on the device performance.