January 18, 2018

STERIS Corporation
Bill Brodbeck
Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K172319
Trade/Device Name: Amsco V-PRO 1 Low Temperature Sterilization System, Amsco V-PRO 1 Plus Low Temperature Sterilization System, V-PRO maX Low Temperature Sterilization System, V-PRO 60 Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: December 8, 2017
Received: December 11, 2017

Dear Bill Brodbeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

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

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172319

Device Name
AMSCO V-PRO® 1 Low Temperature Sterilization System, AMSCO V-PRO® 1 Plus Low Temperature Sterilization System, V-PRO® maX Low Temperature Sterilization System

Indications for Use *(Describe)*
The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems 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 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.

The V-PRO 1 Plus and V-PRO maX Sterilizers' 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 V-PRO maX Sterilizer's 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 V-PRO 1, V-PRO 1 Plus and V-PRO maX Sterilizers' 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
• 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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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172319

Device Name
V-PRO® 60 Low Temperature Sterilization System

Indications for Use *(Describe)*
The V-PRO 60 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 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.

The V-PRO 60 Sterilizer's 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 and one pouch for a total weight of 12 lbs (5.4 kg).

The V-PRO 60 Sterilizer's 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) and mat without additional load. The flexible endoscope may be a single or dual lumen device with lumens that are > 1 mm (~3/64") ID and < 990 mm (38-63/64") in length.
@ The validation studies were conducted using a validation load consisting of one instrument tray containing one flexible endoscope, with silicone mat, instrument organizers and light cord (if not integral to scope).

The V-PRO 60 Sterilizer's 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") internal diameter (ID) and ≤ 410 mm (16-9/64") in length
• Triple channeled devices with stainless steel lumens that are either:
≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-55/64") 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) 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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510(k)
Summary For
K172319
Amsco V-PRO 1 Low Temperature Sterilization System
Amsco V-PRO 1 Plus Low Temperature Sterilization System
V-PRO maX Low Temperature Sterilization System
V-PRO 60 Low Temperature Sterilization System

STERIS Corporation
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Contact: Bill Brodbeck
Director, Regulatory Affairs
Tel: 440-392-7690
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Submission Date: July 31, 2017

1. Device Name

Trade Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System
V-PRO™ maX Low Temperature Sterilization System
V-PRO™ 60 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

The claimed primary predicate device is the V-PRO maX Low Temperature Sterilization System, cleared most recently under **K162413**.

Reference devices are included in this submission as the V-PRO maX cleared indications for use includes claims for the following proposed reference devices:

- Amsco® V-PRO™ 1 Low Temperature Sterilization System (**K062297**)
- Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System (**K083097**, **K102394, K111810** and **K160433**)

The V-PRO™ maX Low Temperature Sterilization System prior clearances include Premarket Submissions **K102330**, **K112760**, **K112813**, **K120632** and **K131120**.

The V-PRO 60 Low Temperature Sterilization System also cleared most recently under **K162413**.

The purpose of this submission is to describe modifications to labeling of the V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Low Temperature Sterilization Systems. The proposed modifications involve (1) addition of compatible materials contained within devices to be processed by the subject devices, and (2) revision of the indications for use statements of the subject devices strictly for clarity and conciseness.

3. Description of Device

The V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Low Temperature Sterilization Systems, using VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The Sterilizers use VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). 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.

The V-PRO 1, V-PRO 1 Plus, and the V-PRO maX and V-PRO 60 Low Temperature Sterilization Systems are programmed to enact one (the Lumen Cycle), two (the Lumen Cycle and the Non Lumen Cycle) or three (the Lumen Cycle, the Non Lumen Cycle and the Flexible Cycle) cycles, respectively.

4. Intended Use

V-PRO 1, V-PRO 1 Plus and V-PRO maX

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems 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 temperature, suitable for processing medical devices.

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.

The V-PRO 1 Plus and V-PRO maX Sterilizers' 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 V-PRO maX Sterilizer's 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 load 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 V-PRO 1, V-PRO 1 Plus and V-PRO maX Sterilizers' 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
- 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).

V-PRO 60

The V-PRO 60 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 low temperature, suitable for processing medical devices without leaving toxic residues.

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

The V-PRO 60 Sterilizer's 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 and one pouch for a total weight of 12 lbs (5.4 kg).

The V-PRO 60 Sterilizer's 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) and mat without 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.

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

The V-PRO 60 Sterilizer's 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 internal diameter (ID) and ≤ 410 mm in length
- Triple channeled devices with stainless steel 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 twelve (12) 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).

5. Description of Safety and Substantial Equivalence

The V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Sterilizers are the same as the predicate devices except for the specific requested changes to labeling and indications for use statements. There are no differences in technology (including features, materials, and principles of operation) between the proposed and predicate devices. Therefore, the differences between the proposed and predicate devices are limited to the addition of device materials claimed to be compatible for processing in the device and changes to the indications for use statements for the purposes of clarity and conciseness.

The following table summarizes the verification activity that was performed with its respective acceptance criteria to ensure that this modification does not affect the safety or effectiveness of the V-PRO 1, V-PRO 1 Plus, V-PRO maX or V-PRO 60 Low Temperature Sterilization Systems.

Test	Acceptance Criteria	Results
Determination of Worst Case (Most Resistant) Material for VHP	Test The most resistant material (MRM) is the material that is most difficult to sterilize (the material with the largest number of non-sterile results) Controls Controls shall perform as intended.	**Pass** As identified within previous V-PRO Sterilizer submissions, the most resistant material (MRM) for surface sterilization is Kraton.
Medical Device Material Compatibility	• The devices shall be processed for 50 V-PRO 60 Sterilizer Lumen Cycles (worst case) • The devices shall show no structural defects (crazing, cracks or chipping). • The devices shall function following processing.	**Pass** This testing verified compatibility of the tested 20 materials with the V-PRO Sterilizers.
Cytotoxicity Evaluation of Medical Devices	• All Worst Case Cycles shall proceed to completion. • The cytotoxic endpoint for each medical device shall be determined. • Cytotoxicity Assay Controls shall preform as intended	**Pass** Testing demonstrates that various medical devices containing were determined to be non-cytotoxic following processing in three (3) V-PRO 60 Sterilizer Lumen Cycles:
Hydrogen Peroxide Residual Analysis of Processed Medical Devices	• The residual hydrogen peroxide level for each medical device shall be determined and compared to the allowable hydrogen peroxide limits for mucosal and internal tissue contact. • Each device shall demonstrate exhaustive extraction by showing less than a 10% increase for two (2) consecutive sample time points. • Hydrogen Peroxide Residual Analysis Controls shall perform as intended.	**Pass** Testing demonstrates that the hydrogen peroxide residuals from the medical devices composed of the 19 proposed compatible materials are from 2660-fold lower to greater than 13,000-fold lower than the tolerable exposure limits for mucosal and internal tissue contact when processed in three (3), worst case, back-to-back Lumen Cycles in the V-PRO 60 Sterilizer.

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device (K162413, Class II (21 CFR 880.6860), product code MLR.