K140498

STERIS®

JUL 24 2014

510(k) Summary
For
V-PRO® 60 Low Temperature Sterilization System

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Summary Date: July 24, 2014

1. Device Name

Trade Name:	V-PRO® 60 Low Temperature Sterilization System
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas 21 CFR 880.6860 Product Code MLR
Device Class:	Class II

2. Predicate Devices

Amsco V-PRO maX Low Temperature Stetilization System (K131120). Please note that the predicate device was originally cleared under K102330.

A comparison between the proposed V-PRO 60 Low Temperature Sterilization System to the predicate device is summarized in the table below.

Feature	V-PRO 60 Low Temperature Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K131120)
Indications for Use	The V-PRO 60 Low Temperature Sterilization System, with VAPROX® HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture. The V-PRO 60 Sterilizer's **Lumen Cycle** can sterilize:[a] • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:[a]	The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The three pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture. The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization System's **Lumen Cycle**, can sterilize:[a] • Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:[a] o single channeled devices with a stainless steel lumen that is ≥ 0.77 mm internal diameter (ID) and ≤

Feature	V-PRO 60 Low Temperature Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K131120)
	o single or dual lumen devices with stainless lumens that are ▪ ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length o triple lumen devices with stainless steel lumens that are ▪ ≥ 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 [a] The validation studies for all lumen configurations were 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 with instrument organizers and mat and two pouches for a total weight of 11 lbs (5.0 kg). The V-PRO 60 Sterilizer's **Non Lumen Cycle** can sterilize: [b] • Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors. [b] The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lbs (5.4 kg). The V-PRO 60 Sterilizer's **Flexible Cycle** can sterilize: [c] • One flexible surgical endoscope or bronchoscope with a light cord (if not	500 mm in length o dual lumen devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length o triple lumen devices with stainless steel lumens that are ▪ ≥ 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 [a] The validation studies for all channel/ lumen configurations were conducted using a maximum of twenty (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. The Amsco V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' **Non Lumen Cycle,** cleared under K083097, K102394 and K111810, can sterilize:[b] • Non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors. [b] The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs. The Amsco V-PRO maX Low Temperature Sterilization System's **Flexible Cycle,** cleared under K102330 and K112760, can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two load configurations: 1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c]

Feature	V-PRO 60 Low Temperature Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K131120)
	integral to endoscope) and mat without any additional load. The flexible endoscope may be a: o single or dual lumen device with lumens that are ≥ 1 mm (~3/64") ID and ≤ 990 mm (38-63/64") in length [c] The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.	The flexible endoscopes may contain either: o a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length o or two lumens with: one lumen that is ≥ 1 mm ID and ≤ 998 mm in length and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length [c] 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 including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d] The flexible endoscope can contain either: • a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • or two lumens with: a single lumen that is ≥ 1 mm ID and ≤ 998 mm in length and the other lumen that is ≥ 1 mm and ≤ 850 mm in length [d] 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 load weight of 24.0 lbs.
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

Feature	V-PRO 60 Low Temperature Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K131120)
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 indefinitely. The software allows user selection of either the Lumen, Non Lumen, or Flexible pre-programmed cycle.	Programmable Logic Control (PLC). The software allows user selection of either the Lumen, Non Lumen, or Flexible pre-programmed cycle.
Total Cycle Time	Lumen Cycle - 60 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 38 minutes	Lumen Cycle - 55 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 35 minutes
Sterilant	VAPROX HC Sterilant (59% Hydrogen Peroxide). The same amount of sterilant is injected for each of the sterilization pulses for all three cycles.	VAPROX HC Sterilant (59% Hydrogen Peroxide). The same amount of sterilant is injected for each of the sterilization pulses for all three cycles.
Accessories	Accessories were submitted under separate, individual, concurrent 510(k)s and cover the following: • Self-contained biological indicator and biological indicator challenge pack • Chemical indicator • Trays & Tray Accessories • Pouches	The following accessories are available for the V-PRO maX Low Temperature Sterilization System • Self-contained biological indicator • Biological indicator challenge pack • Chemical indicator • Trays & Tray Accessories • Pouches

The proposed device has an intended use similar to the predicate with the same technological characteristics. Although, the devices slightly differ, the provided descriptive characteristics and performance data demonstrate equivalence. Therefore, the proposed V-PRO 60 Low Temperature Sterilization System is substantially equivalent to the predicate device, the V-PRO maX Low Temperature Sterilization System.

3. Description of Device

The V-PRO 60 Low Temperature Sterilization System is a new vaporized hydrogen peroxide sterilizer model to be added to the STERIS V-PRO family of sterilizers. The V-PRO product line currently consists of the Amsco V-PRO 1, Amsco V-PRO 1 Plus and Amsco V-PRO maX Sterilizers.

As with the predicate device (K102330), the V-PRO 60 Sterilizer has three pre-programmed cycles: the Lumen Cycle, the Non Lumen Cycle and the Flexible Cycle. The V-PRO 60 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 60 Sterilizer uses VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). Its three pre-programmed cycles all utilize 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.

4. Intended Use

The V-PRO 60 Low Temperature Sterilization System, with VAPROX HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 60 Sterilizer's **Lumen Cycle** can sterilize: [a]

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: [a]
  - single or dual lumen devices with stainless steel lumens that are
    - ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length
  - triple lumen devices with stainless steel lumens that are
    - ≥ 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

[a] The validation studies for all lumen configurations were 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 with instrument organizers and mat and two pouches for a total weight of 11 lbs (5.0 kg).

The V-PRO 60 Sterilizer's **Non Lumen Cycle** can sterilize [b]

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

[b] The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lbs (5.4 kg).

The V-PRO 60 Sterilizer's **Flexible Cycle** can sterilize:[c]

- One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any 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

[c] The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.

5. Summary of Nonclinical Tests

The V-PRO 60 Low Temperature Sterilization System has the same or similar intended use and the same technological characteristics as compared to the predicate device. Performance testing to assess and demonstrate substantial equivalence to the predicate is summarized below.

Test	Result	Conclusion
AOAC Sporicidal Test	All 720 carriers processed using 3 lots of EOSL sterilant were sterile.	PASS
Determination of D-value and Total Kill Endpoint	Greater than a 12 log reduction of the most resistant organism is achieved within all cycle (Lumen Cycle, Non Lumen Cycle and Flexible Cycle) of the V-PRO 60 Sterilizer.	PASS
½ Cycle Modified Total Kill Endpoint Verification	Modified total kill end point analysis was demonstrated for all three V-PRO 60 Sterilizer cycles. The standard injection weight of 1.1 g and at least one lower injection weight resulted in all sterile results within the validation load used to qualify each sterilizer cycle. Partial positives or all survive results were seen at lower injection weights.	PASS
½ Cycle Sterilization Verification of Cycle Claims	• The Lumen Cycle reproducibly sterilizes single, dual and triple lumen devices under worst case conditions in ½ Cycle • The Flexible Cycle reproducibly sterilizes 1 x 990 mm flexible endoscope lumens under worst case conditions in ½ Cycle • The Non Lumen Cycle reproducibly sterilizes non-lumened devices under worst case conditions in ½ Cycle	PASS

Test	Result	Conclusion
½ Cycle Verification of Mated Surfaces	Sterile efficacy was demonstrated for mated surfaces under worst case conditions	PASS
Simulated Use Test	Simulated use testing verified the ability of the V-PRO 60 Sterilizer cycles to sterilize medical devices under worst case processing conditions.	PASS
In Use Test	The in use investigation demonstrated the ability of the V-PRO 60 Sterilizer cycles to sterilize patient-soiled, clinically-cleaned, medical instruments.	PASS
Biocompatibility	Cytotoxicity and residue analysis of 23 materials have demonstrated biocompatibility after processing in the V-PRO 60 Sterilizer.	PASS
Medical Device Material Compatibility	Evaluation of medical devices after multiple cycles in the V-PRO 60 Sterilizer has demonstrated compatibility with 23 materials of construction.	PASS
Final Process Qualification	The V-PRO 60 Sterilizer final process qualification was successful for all three (3) sterilizer cycles. All three lots of CI exhibited complete color change. All three SCBI PIs exhibited a passing color change and all SCBIs were negative for growth. Manual inspection of the process parameter data confirmed that all cycle specifications were met.	PASS

The V-PRO 60 Low Temperature Sterilization System has been tested for conformity and is certified to the following standards:

- EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements; Part 1: General Requirements
- EN61326-1:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

6. Conclusion

The V-PRO 60 Low Temperature Sterilization System's Lumen, Non Lumen and Flexible Cycles have been validated to meet the established performance criteria. The results of the V-PRO 60 Low Temperature Sterilization System verification studies demonstrate that the sterilizer performs as intended and the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center - WO66-G609
Silver Spring, MD 20993-000

July 24, 2014

STERIS Corporation
Dr. William Brodbeck
Director, Regulatory Affairs
5960 Heisley Road
Mentor, OH 44060

Re: K140498
Trade/Device Name: V-Pro 60 Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Sterilizer, Ethylene Oxide Gas
Regulatory Class: II
Product Code: MLR
Dated: June 24, 2014
Received: June 25, 2014

Dear Dr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140498

Device Name: **V-PRO® 60 Low Temperature Sterilization System**

Indications For Use:

The V-PRO 60 Low Temperature Sterilization System, with VAPROX® HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in Healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 60 Sterilizer's **Lumen Cycle** can sterilize: [a]

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: [a]
  - single or dual lumen devices with stainless steel lumens that are
    - ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length
  - triple lumen devices with stainless steel lumens that are
    - ≥ 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

[a] The validation studies for all lumen configurations were 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 with instrument organizers and mat and two pouches for a total weight of 11 lbs (5.0 kg).

The V-PRO 60 Sterilizer's **Non Lumen Cycle** can sterilize [b]

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

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[b] The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lbs (5.4 kg).

The V-PRO 60 Sterilizer's **Flexible Cycle** can sterilize:[c]

- One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any 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

[c] The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
Date: 2014.07.24 12:48:52 -04'00'