January 3, 2019

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

Re: K182568
Trade/Device Name: V-PRO s2 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: November 26, 2018
Received: November 27, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Elizabeth F. Claverie -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182568

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
- 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
  - ≥ 2 mm (~5/64”) ID and ≤ 400 mm (~15 3/4”) in length
  - ≥ 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

@ 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") 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 (~10-53/64") 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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)*

K182568

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 and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

The V-PRO 60 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 60 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 (~3/64") ID and ≤ 990 mm (38-63/64") in length.
- Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions
  - ≥ 2 mm (~5/64") ID and ≤ 400 mm (~15 3/4") in length
  - ≥ 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

@ 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 60 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") 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 (~10-53/64") 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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510(k) Summary
For
V-PRO® s2 and V-PRO 60 Low Temperature Sterilization Systems

K182568

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

Contact: Bill Brodbeck
Director, Regulatory Affairs

Telephone: (440) 392-7690
Fax No: (440) 357-9198

Summary Date: November 26, 2018

1. Device Name

K#:	K182568
Trade Name:	V-PRO® s2 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 Devices

V-PRO® 60 Low Temperature Sterilization System (originally cleared under K140498 with additional material compatibility claims cleared under K162413 and most recently, **K172319**)

A comparison between the proposed V-PRO s2 Low Temperature Sterilization System to the predicate device is summarized in the table below.

Feature	V-PRO s2 Low Temperature Sterlization System (Proposed Device)	V-PRO 60 Low Temperature Sterlization System (Predicate Device/K172319)
Indications for Use	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	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

Feature	V-PRO s2 Low Temperature Sterlization System (Proposed Device)	V-PRO 60 Low Temperature Sterlization System (Predicate Device/K172319)
	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 • 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 (~3/64") ID and ≤ 990 mm (38-63/64") in length. • Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions o ≥ 2 mm (~5/64") ID and ≤ 400 mm (~15 3/4") in length o ≥ 0.76 mm (~1/32") ID and ≤ 233	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).

Feature	V-PRO s2 Low Temperature Sterlization System (Proposed Device)	V-PRO 60 Low Temperature Sterlization System (Predicate Device/K172319)
	mm (~9 11/64") in length o ≥ 1.0 mm (~3/64") ID and ≤ 254 mm (~10") 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 internal diameter (ID) and ≤ 410 mm 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).	
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 s2 Low Temperature Sterlization System (Proposed Device)	V-PRO 60 Low Temperature Sterlization System (Predicate Device/K172319)
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, or Flexible pre-programmed cycle.
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
Sterilant	VAPROX HC Sterilant (59% Hydrogen Peroxide). 1.1 g of sterilant is used for each sterilant injection for all four cycles.	VAPROX HC Sterilant (59% Hydrogen Peroxide). 1.1 g of sterilant is used for each sterilant injection for all three cycles
Accessories	Accessories are to be submitted under separate, individual, 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 are to be submitted under separate, individual, 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

The proposed device has an intended use similar to the predicate with the same technological characteristics. The indications for use differ between the two devices with the proposed device carrying the additional Fast Cycle, removal of restrictions on claims regarding diffusion-restricted spaces for all cycles, increased maximum load capacity claims for the Non Lumen Cycle and expanded load claims for the Flexible Cycle. Additional convenience features have also been included with the proposed device. Although, the devices slightly differ in their design and additional convenience items and features, the provided descriptive characteristics and performance data demonstrate equivalence. Therefore, the proposed V-PRO s2 Low Temperature Sterilization System is substantially equivalent to the predicate device, the V-PRO 60 Low Temperature Sterilization System.

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

Feature	V-PRO 60 Low Temperature Sterlization System (Proposed Device)	V-PRO 60 Low Temperature Sterlization System (Predicate Device/K172319)

Feature	V-PRO 60 Low Temperature Sterlization System (Proposed Device)	V-PRO 60 Low Temperature Sterlization System (Predicate Device/K172319)
Indications for Use	The V-PRO® s 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 and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. The V-PRO 60 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 60 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 (~3/64") ID and ≤ 990 mm (38-63/64") in length. • Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions o ≥ 2 mm (~5/64") ID and ≤ 400 mm (~15 3/4") in length o ≥ 0.76 mm (~1/32") ID and ≤ 233 mm (~9 11/64") in length o ≥ 1.0 mm (~3/64") ID and ≤ 254 mm (~10") 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	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

Feature	V-PRO 60 Low Temperature Sterlization System (Proposed Device)	V-PRO 60 Low Temperature Sterlization System (Predicate Device/K172319)
	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 60 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") 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 (~10-53/64") 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).	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).
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 60 Low Temperature Sterlization System (Predicate Device/K172319)
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.	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.
Total Cycle Time	Lumen Cycle - 60 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 38 minutes	Lumen Cycle - 60 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 38 minutes
Sterilant	VAPROX HC Sterilant (59% Hydrogen Peroxide). 1.1 g of sterilant is used for each sterilant injection for all three cycles.	VAPROX HC Sterilant (59% Hydrogen Peroxide). 1.1 g of sterilant is used for each sterilant injection for all three cycles.
Accessories	Accessories are 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, 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

The proposed device has an intended use identical to the predicate with the same technological characteristics. The indications for use differ between the two devices with the proposed device's removal of restrictions on claims regarding diffusion-restricted spaces for all cycles, increased maximum load capacity claims for the Non Lumen Cycle and expanded load claims for the Flexible Cycle. Although, the cycle claims slightly differ, the performance data and descriptive characteristics demonstrate equivalence. Therefore, the proposed V-PRO 60 Low Temperature Sterilization System is substantially equivalent to the predicate device.

3. Description of Devices

The V-PRO s2 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 V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2 and V-PRO 60 Sterilizers.

The V-PRO s2 Sterilizer contains the same three sterilization cycles as the predicate device (K172319), the Lumen, Non Lumen and Flexible Cycles, with a new cycle, the Fast Cycle. In addition, compared to the claimed predicate device, the proposed

device contains a cabinetry modification, adds additional claims for devices that may be processed in the Flexible Cycle, and increases the maximum claimed load weight for the Non Lumen Cycle.

The V-PRO 60 Low Temperature Sterilization System is a vaporized hydrogen peroxide sterilizer model that currently exists in the STERIS V-PRO family of sterilizers. The current proposed device claims are intended to modify the indications for use statement.

As with the predicate device (K172319), the V-PRO 60 Sterilizer has three pre-programmed cycles: the Lumen Cycle, the Non Lumen Cycle and the Flexible Cycle, none of which are being altered. The V-PRO 60 Low Temperature Sterilization System is intended for terminal sterilization of cleaned, rinsed, dried and packaged surgical instruments used in healthcare facilities.

The V-PRO s2 and V-PRO 60 Low Temperature Sterilization Systems are 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 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

V-PRO s2 Low Temperature Sterilization System
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
- 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 (12-31/64") mm 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 (~3/64") ID and ≤ 990 mm (38-63/64") in length.
- Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions
  - ≥ 2 mm (~5/64") ID and ≤ 400 mm (~15 3/4") in length
  - ≥ 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

@ 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") 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 (~10-53/64") 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).

V-PRO 60 Low Temperature Sterilization System
The V-PRO® s 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 and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

The V-PRO 60 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 60 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 (~3/64") ID and ≤ 990 mm (38-63/64") in length.
- Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions
    - ≥ 2 mm (~5/64") ID and ≤ 400 mm (~15 3/4") in length
    - ≥ 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

@ 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 60 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") 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 (~10-53/64") 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).

5. Summary of Nonclinical Tests

The V-PRO s2 Low Temperature Sterilization System has the same intended use and similar but not identical technological characteristics that do not raise different questions of safety and effectiveness as compared to the predicate device. 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
Determination of D-value and Total Kill Endpoint	Greater than a 12 log reduction of the most resistant organism is achieved within Fast, Non Lumen and Flexible Cycles of the V-PRO s2 Sterilizer.	PASS
½ Cycle Modified Total Kill Endpoint Verification	Modified total kill end point analysis was demonstrated for Non Lumen and Flexible V-PRO s2 and V-PRO 60 Sterilizer cycles and for the Fast V-PRO s2 Sterilizer cycle. The standard injection weight of 1.1 g and at least one lower injection weight resulted in all sterile results for all cycles.	PASS
½ Cycle Sterilization Verification of Surfaces	Verified surface sterilization efficacy for the most resistant material for VHP within a worst-case validation load in the V-PRO s2 Sterilizer Fast ½ Cycle and the V-PRO 60 Non Lumen Cycle.	PASS
½ Cycle Verification of Mated Surfaces	Sterile efficacy was demonstrated for mated surfaces under worst case conditions in the Fast and Non Lumen V-PRO s2 Sterilizer cycles.	PASS
Simulated Use Test	Simulated use testing verified the ability of the Sterilizer cycles to sterilize medical devices under worst case processing conditions in the V-PRO s2 and V-PRO 60 Non Lumen and Flexible Cycles and in the V-PRO s2 Fast Cycle.	PASS

Test	Result	Conclusion
In Use Test	The in use investigation demonstrated the ability of the V-PRO s2 and V-PRO 60 Sterilizer Flexible Cycle and the V-PRO s2 Fast Cycle to sterilize patient-soiled, clinically-cleaned, medical instruments.	PASS
Biocompatibility	Cytotoxicity and residue analysis of worst case materials have demonstrated biocompatibility after processing in the V-PRO s2 Sterilizer's Fast Cycle.	PASS
Final Process Qualification	The V-PRO s2 Sterilizer final process qualification was successful for the Fast Cycle.	PASS

The V-PRO s2 Low Temperature Sterilization System has been tested for conformity and is certified to the following standards:

- IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements; Part 1: General Requirements

- IEC 61010-2-040: 2015 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

- IEC 61326-1:2006 (V-PRO 60) or 2012 (V-PRO s2) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – EMC requirements - Part 1: General Requirements

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject devices are as safe, as effective and performs at least as well as the legally marketed predicate device K172319, Class II (21 CFR 880.6860), product code MLR.