May 9, 2019

STERIS Corporation
Anthony Piotrkowski
Director Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K190917
Trade/Device Name: V-PRO 60 Low Temperature Sterilization Systems, V-PRO s2 Low Temperature Sterilization Systems
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: April 8, 2019
Received: April 9, 2019

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/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,

For David Krause, PhD
Acting 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

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)*

K190917

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*

K190917

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”) internal diameter (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
  ≥ 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
  ≥ 1.8mm (~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 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”) ID and ≤ 410 mm (16-9/64”) in length
  ≥ 1.8 mm (~5/64") ID x ≤ 542 mm (~21-5/16") 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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510(k) Summary For

V-PRO® 60 Low Temperature Sterilization Systems and V-PRO®s2 Low Temperature Sterilization Systems

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
Fax No: (440) 357-9198

Summary Date: May 8, 2019

Premarket Notification Number: K190917

1. Device Name

Trade Name:	V-PRO® 60 Low Temperature Sterilization Systems and 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

2. Predicate Devices

Primary Predicate: **K182568**	V-PRO® s2 and V-PRO® 60 Low Temperature Sterilization Systems
Reference Device: **K190103**	V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® maX 2 Low Temperature Sterilization Systems

3. Description of Devices

The V-PRO s2 Sterilizer contains the same three sterilization cycles as V-PRO 60 Sterilizer (the Lumen, Non Lumen and Flexible Cycles) with one additional cycle (the Fast Cycle). The V-PRO s2 Sterilizer contains a cabinetry modification and is free-standing as opposed to the cart-mounted V-PRO 60 Sterilizer.

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.

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 / Indications for 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
  ≥ 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 (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

≥ 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 and ≥ 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).

V-PRO 60 Low Temperature Sterilization System
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") internal diameter (ID) and ≤ 990 mm (38-63/64") in.
- 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 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") 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).

5. Technological Characteristics

Shown below is a comparison between the modified V-PRO s2 Low Temperature Sterilization System to the predicate device.

Feature	V-PRO s2 Low Temperature Sterilization System (Modified Device)/K190917	V-PRO s2 Low Temperature Sterilization System (Predicate Device/K182568)

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 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.

Feature	V-PRO s2 Low Temperature Sterilization System (Modified Device/K190917)	V-PRO s2 Low Temperature Sterilization System (Predicate Device/K182568)
	‡ 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 (~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	‡ 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 (~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

Feature	V-PRO s2 Low Temperature Sterilization System (Modified Device/K190917)	V-PRO s2 Low Temperature Sterilization System (Predicate Device/K182568)
	≥ 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 internal diameter (ID) and ≤ 410 mm 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).	○ ≥ 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 Sterilization System (Modified Device/K190917)	V-PRO s2 Low Temperature Sterilization System (Predicate Device/K182568)
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 Fast Cycle - 19 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 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

The proposed device is identical to the predicate except for modification to the indications for use to allow sterilization of single and dual lumen stainless steel lumened devices with the following dimensions: ≥ 1.8 mm ID x ≤ 542 mm length in the Lumen, flexible and fast cycles. Note that with the addition of the 1.8mm x 542mm stainless steel lumen claim, the previous claim (2mm ID x 400mm length) that falls within the new claim has been removed from the Flexible Cycle.

Shown below is comparison of the modifications to the V-PRO 60 Low Temperature Sterilization System to the most recently cleared predicate device.

Feature	V-PRO 60 Low Temperature Sterilization System (Proposed Device/K190917)	V-PRO 60 Low Temperature Sterilization System (Predicate Device/K182568)
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-	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-

Feature	V-PRO 60 Low Temperature Sterilization System (Proposed Device/K190917)	V-PRO 60 Low Temperature Sterilization System (Predicate Device/K182568)
	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 ≥ 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 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	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 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

Feature	V-PRO 60 Low Temperature Sterilization System (Proposed Device/K190917)	V-PRO 60 Low Temperature Sterilization System (Predicate Device/K182568)
	≥ 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 ^ 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).	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).
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
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
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Feature	V-PRO 60 Low Temperature Sterilization System (Proposed Device/K190917)	V-PRO 60 Low Temperature Sterilization System (Predicate Device/K182568)
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

The proposed device is identical to the predicate except for modification to the indications for use to allow sterilization of single and dual lumen stainless steel lumened devices with the following dimensions: ≥ 1.8 mm ID x ≤ 542 mm length in the Lumen, flexible and fast cycles. Note that with the addition of the 1.8mm x 542 mm stainless steel lumen claim, the previous claim (2mm ID x 400mm length) that falls within the new claim has been removed from the Flexible Cycle.

The Reference Devices, V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® maX 2 Low Temperature Sterilization Systems are 136 L chamber sterilizers. They have the same technological characteristics, mechanism of action and intended use as the proposed devices were cleared in K190103 for the same modification to the indications for use described in this submission.

6. Summary of Nonclinical Tests

The modified sterilizers have the same intended use and same technological characteristics as the predicate devices. Performance testing for the subject device were identical to the methods used to validate predicate device. Shown below is a summary of those methods below.

Test	Result	Conclusion
½ Cycle Modified Total Kill Endpoint Verification	½ Cycle modified total kill end point analysis was demonstrated for the 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
Simulated Use Test	Simulated use testing verified the ability of the sterilizer cycles to sterilize medical devices under worst-case processing conditions.	PASS

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the V-PRO® 60 Low Temperature Sterilization System and 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 K182568, Class II (21 CFR 880.6860), product code MLR.