September 9, 2022

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

Re: K222093
Trade/Device Name: V-PRO maX 2 Low Temperature Sterilization System, V-PRO maX Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: August 17, 2022
Received: August 18, 2022

Dear Anthony Piotrkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Clarence W. Murray, III, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K222093

Device Name
V-PRO maX Low Temperature Sterilization System

Indications for Use *(Describe)*

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

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

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

The V-PRO maX Sterilizer's Flexible Cycle can sterilize:
Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:
1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. * The flexible endoscopes may contain single or dual channel lumens that are ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length.
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
2. One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories and mat, and additional instruments. †† The flexible endoscope may contain single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length
 Additional instruments may include non-lumened or lumened medical devices with the following configurations:
Single, dual or triple channel stainless steel lumen that is ≥ 0.48 mm ID and ≤ 100 mm in length
†† The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs (11 kg).

The V-PRO maX Sterilizers' Lumen Cycle can sterilize: † Medical devices with the following configurations:
• Single, dual or triple channeled stainless steel lumen that are:
• ≥ 0.77 mm ID and ≤ 527 mm in length
• ≥ 0.8 mm ID and ≤ 542 mm in length
• ≥ 0.48 mm ID and ≤ 100 mm in length
• Dead end lumen that is ≥ 1.3 mm ID and ≤ 73 mm in length
• Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) that are:
• ≥ 3 mm ID and ≤ 298 mm in length
• ≥ 4 mm ID and ≤ 424 mm in length
† Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs (8.9 kg).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
For

V-PRO® maX Low Temperature Sterilization Systems and V-PRO® maX 2 Low Temperature Sterilization Systems

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

Contact: Anthony Piotrkowski
Director, Regulatory Affairs
Tel: 440-392-7437
Fax: 440-357-9198
Email: tony_piotrkowski@steris.com

Submission Date: September 5, 2022

Premarket Notification Number: K222093

1. Device Name

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

2. Predicate Device

The claimed primary predicate device is the V-PRO maX and maX 2 Low Temperature Sterilization Systems, cleared most recently under **K190103**.

Table 5-1. A comparison between the proposed V-PRO maX Low Temperature Sterilization System to the predicate device

Feature	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (Predicate Device – K190103)	V-PRO maX Low Temperature Sterilization System (Modified Device) K222093
Intended Use and Indications for Use	The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems using VAPROX HC Sterilant are intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues. Each Cycle can sterilize non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle. The V-PRO 1 Plus and V-PRO maX Sterilizers' Non Lumen Cycle can sterilize: ‡ Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes. ‡ *The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs (22.7 kg).* The V-PRO maX Sterilizer's Flexible Cycle can sterilize: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two load configurations:	The V-PRO maX Low Temperature Sterilization System using VAPROX HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues. Each Cycle can sterilize non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. The V-PRO maX Sterilizers' Non Lumen Cycle can sterilize: ‡ Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes. ‡ *The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs (22.7 kg).* The V-PRO maX Sterilizer's Flexible Cycle can sterilize: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:

Feature	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (Predicate Device – K190103)	V-PRO maX Low Temperature Sterilization System (Modified Device) K222093
	1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. * The flexible endoscopes may contain either: • A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length • Or two lumens with: ▪ One lumen that is ≥ 1 mm ID and ≤ 990 mm in length ▪ And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length * The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).	1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. * The flexible endoscopes may contain single or dual channel lumens that are ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length. * The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
	2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. †† The flexible endoscope may contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: ▪ One lumen that is ≥ 1 mm ID and ≤ 990 mm in length ▪ And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length. †† The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg).	2. One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories and mat, and additional instruments. †† The flexible endoscope may contain single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length ▪ Additional instruments may include non-lumened or lumened medical devices with the following configurations: ▪ Single, dual or triple channel stainless steel lumen that is ▪ ≥ 0.48 mm ID and ≤ 100 mm in length †† The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs (11 kg).
	The V-PRO 1, V-PRO 1 Plus and V-PRO maX Sterilizers' Lumen Cycle can sterilize: † Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations: • Single channeled devices with a stainless lumen that is ≥ 0.77 mm ID and ≤ 500 mm in length • Single channeled devices with a stainless lumen that is ≥ 1.8 mm ID and ≤ 542 mm in length • Dual channeled devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length • Triple channeled devices with stainless lumens that are either: ≥ 1.2 mm ID and ≤ 275 mm in length ≥ 1.8 mm ID and ≤ 310 mm in length or ≥ 2.8 mm ID and ≤ 317 mm in length † Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs (8.9 kg).	The V-PRO maX Sterilizers' Lumen Cycle can sterilize: † Medical devices with the following configurations: • Single, dual or triple channeled stainless steel lumen that are: • ≥ 0.77 mm ID and ≤ 527 mm in length • ≥ 0.8 mm ID and ≤ 542 mm in length • ≥ 0.48 mm ID and ≤ 100 mm in length • Dead end lumen that is ≥ 1.3 mm ID and ≤ 73 mm in length • Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) that are: • ≥ 3 mm ID and ≤ 298 mm in length • ≥ 4 mm ID and ≤ 424 mm in length † Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs (8.9 kg).

Feature	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (Predicate Device – K190103)	V-PRO maX Low Temperature Sterilization System (Modified Device) K222093
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 proprietary microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains user settings and calibration data indefinitely. Up to 300 cycle data files can be stored for review or downloading by the user. The software allows user selection of either the Lumen, Non Lumen or Flexible pre-programmed cycle.	Control system consists of a proprietary microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains user settings and calibration data indefinitely. Up to 300 cycle data files can be stored for review or downloading by the user. The software allows user selection of either the Lumen, Non Lumen or Flexible pre-programmed cycle.
Total Cycle Time	Lumen Cycle - 55 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 35 minutes	Lumen Cycle - 55 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 35 minutes
Sterilant	VAPROX HC Sterilant (59% Hydrogen Peroxide).	VAPROX HC Sterilant (59% Hydrogen Peroxide).
Accessories	Accessories were submitted under separate, individual, concurrent 510(k)s and cover the following: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape	Accessories were submitted under separate, individual, concurrent 510(k)s and cover the following: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape

Table 5-2. A comparison between the proposed V-PRO maX 2 Low Temperature Sterilization System to the predicate device

Feature	V-PRO maX 2 Low Temperature Sterilization System (Predicate Device/K190103)	V-PRO maX 2 Low Temperature Sterilization System (Modified Device) K222093
Indications for Use	The V-PRO maX 2 Low Temperature Sterilization System using VAPROX HC Sterilant are intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues. **Each Cycle can sterilize** non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle and the Fast Non Lumen Cycle. **The Non Lumen Cycle can sterilize:** ‡ Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.	The V-PRO maX 2 Low Temperature Sterilization System using VAPROX HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues. **Each Cycle can sterilize** non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. **The 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 maX 2 Low Temperature Sterilization System (Predicate Device/K190103)	V-PRO maX 2 Low Temperature Sterilization System (Modified Device) K222093
	‡ The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs (22.7 kg). **The Fast Non Lumen Cycle can sterilize:*** Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes. * The validation studies were conducted using a validation load consisting of one pouched instrument tray for a total weight of 11 lbs (5 kg). **The Flexible Cycle can sterilize:** Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations: 1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain either: • A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length • Or two lumens with: ▪ One lumen that is ≥ 1 mm ID and ≤ 990 mm in length ▪ And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length * The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope). 2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. †† The flexible endoscope may contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: ▪ One lumen that is ≥ 1 mm ID and ≤ 990 mm in length ▪ And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length. †† The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg). **The Lumen Cycle can sterilize:** † Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations: • Single channeled devices with a stainless lumen that is ≥ 0.77 mm ID and ≤ 500 mm in length	‡ The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs (22.7 kg). **The Fast Non Lumen Cycle can sterilize:*** Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes. * The validation studies were conducted using a validation load consisting of one pouched instrument tray for a total weight of 11 lbs (5 kg). **The Flexible Cycle can sterilize:** Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations: 1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain single or dual channel lumens that are ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length. * The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope). 2. One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat and additional non-lumened instruments. †† The flexible endoscope may contain single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length ▪ Additional instruments may include non-lumened or lumened medical devices with the following configurations: ▪ Single, dual or triple channel stainless steel lumen that is ≥ 0.48 mm ID and ≤ 100 mm in length †† The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments, and silicone mat for a total weight of 24 lbs (11 kg). **The Lumen Cycle can sterilize:** † Medical devices with the following configurations: • Single, dual or triple channeled stainless steel lumen that are: • ≥ 0.77 mm ID and ≤ 527 mm in length • ≥ 0.8 mm ID and ≤ 542 mm in length

Feature	V-PRO maX 2 Low Temperature Sterilization System (Predicate Device/K190103)	V-PRO maX 2 Low Temperature Sterilization System (Modified Device) K222093
	• Single channeled devices with a stainless lumen that is ≥ 1.8 mm ID and ≤ 542 mm in length • Dual channeled devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length • Triple channeled devices with stainless lumens that are either: ≥ 1.2 mm ID and ≤ 275 mm in length ≥ 1.8 mm ID and ≤ 310 mm in length or ≥ 2.8 mm ID and ≤ 317 mm in length † Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs (8.9 kg).	• ≥ 0.48 mm ID and ≤ 100 mm in length • Dead end lumen that is ≥ 1.3 mm ID and ≤ 73 mm in length • Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) that are: • ≥ 3 mm ID and ≤ 298 mm in length • ≥ 4 mm ID and ≤ 424 mm in length † Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs (8.9 kg).
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 proprietary microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains user settings and calibration data indefinitely. Up to 300 cycle data files can be stored for review or downloading by the user. The software allows user selection of either the Lumen, Non Lumen, Flexible or Fast Non Lumen pre-programmed cycle.	Control system consists of a proprietary microcomputer control board and peripheral function circuit boards, located within the control housing. A memory backup system maintains user settings and calibration data indefinitely. Up to 300 cycle data files can be stored for review or downloading by the user. The software allows user selection of either the Lumen, Non Lumen, Flexible or Fast Non Lumen pre-programmed cycle.
Total Cycle Time	Lumen Cycle - 52 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 35 minutes Fast Non Lumen Cycle – 16 minutes	Lumen Cycle - 52 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 35 minutes Fast Non Lumen Cycle – 16 minutes
Sterilant	VAPROX HC Sterilant (59% Hydrogen Peroxide). The same amount of sterilant is injected for each of the sterilization pulses for all four cycles. Sterilant Cup is read by an RFID reader.	VAPROX HC Sterilant (59% Hydrogen Peroxide). The same amount of sterilant is injected for each of the sterilization pulses for all four cycles. Sterilant Cup is read by an RFID reader.
Accessories	Accessories were submitted under separate, individual, concurrent 510(k)s and cover the following: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape	Accessories were submitted under separate, individual, concurrent 510(k)s and cover the following: • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape

The proposed and predicate device are identical in all ways except their indications for use and consequently their labeling (operator manual).

3. Description of Device

The V-PRO Low Temperature Sterilization Systems are vaporized hydrogen peroxide sterilizers.

The sterilizers have three or more of the following pre-programmed cycles (the Lumen Cycle, the Non Lumen Cycle, the Flexible Cycle, and the Fast Non Lumen Cycle). The V-PRO Low Temperature Sterilization Systems are intended for terminal sterilization of cleaned, rinsed, dried, and packaged reusable surgical instruments used in healthcare facilities.

The V-PRO Sterilizers use VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). The four pre-programmed cycles all use a conditioning phase, a sterilize phase and an aeration phase. 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

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

The Indications for use are detailed in Tables 5.1 and 5.2 above. The differences between the proposed devices and predicate include:

- Simplification of claims description for the Flexible and Lumen Cycles on both sterilizers
- Addition of stainless steel lumen claims to Flexible Cycle on both sterilizers
- Addition of non-metallic and stainless steel lumen claims to Lumen Cycle on both sterilizers
- Addition of diffusion restricted materials for Non Lumen and Fast Non Lumen Cycles on both sterilizers

5. Technological Characteristics

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

6. Summary of Testing to Support Substantial Equivalence

The proposed devices have the same intended use and the same technological characteristics as the predicate devices. Performance testing to assess and demonstrate substantial equivalence, based on risk assessment of the proposed change to the predicate is summarized below.

Test	Result	Conclusion
½ Cycle Verification of Mated Surfaces	Sterile efficacy was demonstrated for mated surfaces under worst case conditions in the V-PRO Sterilizer cycles.	PASS
½ Cycle Efficacy	The standard injection weight resulted in all sterile results within the validation load used to qualify each sterilizer cycle.	PASS
Simulated Use Test	Simulated use testing verified the ability of the 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 Sterilizer cycles to sterilize patient-soiled, clinically-cleaned, medical instruments.	PASS

7. Conclusions

The V-PRO maX Low Temperature Sterilization System has met the established performance criteria. Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performed as well as the legally marketed predicate device K190103, Class II (21 CFR 880.6860), product code MLR.

The V-PRO maX 2 Low Temperature Sterilization System has met the established performance criteria. Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performed as well as the legally marketed predicate device K190103, Class II (21 CFR 880.6860), product code MLR.