DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 6, 2016

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

Re: K160433
Trade/Device Name: V-PRO® 1 Plus and V-PRO® maX Low Temperature Sterilization Systems
Regulation Number: 21 CFR 880.6860
Regulation Name: Sterilizer, Ethylene Oxide Gas
Regulatory Class: II
Product Code: MLR
Dated: June 9, 2016
Received: June 10, 2016

Dear Dr. Brodbeck:

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

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

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

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160433

Device Name
V-PRO® 1 Plus and V-PRO® maX Low Temperature Sterilization Systems

Indications for Use *(Describe)*

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' Lumen Cycle can sterilize:(a)

- Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: (a)
  - o single channeled devices with a stainless lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length
  - o dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
  - o triple channeled devices with stainless steel lumens that are
    - ≥ 1.2 mm ID and ≤ 275 mm in length
    - ≥ 1.8 mm ID and ≤ 310 mm in length
    - or
    - ≥ 2.8 mm ID and ≤ 317 mm in length

(a) The validation studies for all channel/lumen configurations were conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' Non Lumen Cycle can sterilize: (b)

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

(b) The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 50 lbs.

The V-PRO maX Low Temperature Sterilization System'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 two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. (c)
   The flexible endoscopes 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 that is ≥ 1 mm ID and ≤ 850 mm in length

(c) The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.(d) The flexible endoscope can contain either:
   - a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
   - or two lumens with:
     - one lumen that is ≥ 1 mm ID and ≤ 990 mm in length
     - and the other lumen that is ≥ 1 mm and ≤ 850 mm in length

   (d) The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

The parameters for the three V-PRO Cycles are as follows:

Table 1: Parameters for V-PRO Cycles

Sterilization Cycle	Sterilant injection (g)	# of Injections	Sterilant Exposure Time (min)	Chamber Pressure Prior to Injection (Torr)	Chamber/Vaporizer Temperature (°C)
Lumen	2.1	4	32	0.4	50/60
Non Lumen	2.1	4	12	1	50/60
Flexible	2.1	4	12	0.4	50/60

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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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary
For
V-PRO® 1 Plus and V-PRO® maX Low Temperature Sterilization Systems

K160433

STERIS Corporation
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Phone: (440) 354-2600
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Contact: Bill Brodbeck
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Summary Date: June 9, 2016

1. Device Name

Trade Name: V-PRO® 1 Plus and V-PRO® maX Low Temperature Sterilization Systems

Device Class: Class II

Common/usual Name: Vapor Phase Hydrogen Peroxide Sterilizer

Classification Name: Sterilizer, Ethylene Oxide Gas
21 CFR 880.6860
Product Code MLR

2. Predicate Devices

Primary predicate claimed is V-PRO 1 Plus/ V-PRO maX Low Temperature Sterilization System cleared under K131120.

V-PRO® 1 Plus Low Temperature Sterilization System was originally cleared under K083097 with modifications cleared under K102394, K111810, K112813 and K120632.

V-PRO® maX Low Temperature Sterilization System was originally cleared under K102330 with modifications cleared under K112760, and K120632.

Comparison between the proposed V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems to the predicate devices is summarized in the table below.

Feature	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Proposed Device)	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Predicate Devices/K131120)
Indications for Use	The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The three pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture. The V-PRO 1, V-PRO 1 Plus and V-PRO	The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The three pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture. The Amsco V-PRO 1, V-PRO 1 Plus and

Feature	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Proposed Device)	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Predicate Devices/K131120)
	maX Low Temperature Sterilization System's **Lumen Cycle**, can sterilize:[a] • Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: [a] o single channeled devices with a stainless steel lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length o dual lumen devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length o triple lumen devices with stainless steel lumens that are ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length or ▪ ≥ 2.8 mm ID and ≤ 317 mm in length [a] The validation studies for all channel/ lumen configurations were conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.	V-PRO maX Low Temperature Sterilization System's **Lumen Cycle**, can sterilize:[a] • Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: [a] o single channeled devices with a stainless steel lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length o dual lumen devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length o triple lumen devices with stainless steel lumens that are ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length or ▪ ≥ 2.8 mm ID and ≤ 317 mm in length [a] The validation studies for all channel/ lumen configurations were conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.
	The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' **Non Lumen Cycle,** the subject of this submission, can sterilize:[b] • Non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel or titanium diffusion-restricted areas such as the hinged portion of forceps or scissors. [b] The validation studies were conducted using a validation load consisting of two instrument trays for a total weight	The Amsco V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' **Non Lumen Cycle,** cleared under K083097, K102394 and K111810, can sterilize:[b] • Non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors. [b] The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

Feature	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Proposed Device)	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Predicate Devices/K131120)
	of 50.0 lbs. The V-PRO maX Low Temperature Sterilization System'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 two load configurations: 1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c] The flexible endoscopes may contain either: o a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length o or two lumens with: one lumen that is ≥ 1 mm ID and ≤ 990 mm in length and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length [c] The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope). 2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d] The flexible endoscope can contain either: • a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • or two lumens with: a single lumen that is ≥ 1 mm ID and ≤ 990 mm in length and the other lumen that is ≥ 1 mm and ≤ 850 mm in length [d] The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.	The Amsco V-PRO maX Low Temperature Sterilization System's **Flexible Cycle,** cleared under K102330 and K112760, can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two load configurations: 1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c] The flexible endoscopes may contain either: o a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length o or two lumens with: one lumen that is ≥ 1 mm ID and ≤ 998 mm in length and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length [c] The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope). 2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d] The flexible endoscope can contain either: • a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • or two lumens with: a single lumen that is ≥ 1 mm ID and ≤ 998 mm in length and the other lumen that is ≥ 1 mm and ≤ 850 mm in length [d] The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

Feature	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Proposed Device)	V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Predicate Devices/K131120)
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	Programmable Logic Control (PLC). The software allows user selection of either the Lumen, Non Lumen, or Flexible pre-programmed cycle.	Programmable Logic Control (PLC). The software allows user selection of either the Lumen, Non Lumen, or Flexible pre-programmed cycle.
Total Cycle Time	Lumen Cycle - 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). The same amount of sterilant is injected for each of the sterilization pulses for all three cycles.	VAPROX HC Sterilant (59% Hydrogen Peroxide). The same amount of sterilant is injected for each of the sterilization pulses for all three cycles.
Accessories	The following accessories are available for the V-PRO maX Low Temperature Sterilization System • Self-contained biological indicator • Biological indicator challenge pack • Chemical indicator • Trays & Tray Accessories • Pouches	The following accessories are available for the V-PRO maX Low Temperature Sterilization System • Self-contained biological indicator • Biological indicator challenge pack • Chemical indicator • Trays & Tray Accessories • Pouches

The proposed devices have an intended use similar to the predicates with the same technological characteristics. Although, the indications differ slightly, the provided performance data demonstrate equivalence. Therefore, the proposed V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems are substantially equivalent to the predicate devices, the V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems.

3. Description of Device

The V-PRO 1 Plus and V-PRO maX Sterilizers use VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). Devices that meet the criteria described within the indications for use and composed of compatible materials are placed within the sterilization chamber and the appropriate cycle selected through the graphic user interface. The pre-programmed cycles all utilize a conditioning phase which prepares the chamber, a sterilize phase in which loaded devices are exposed to the sterilizing agent, VHP, at low pressure and an aeration phase to remove residual hydrogen peroxide. The packaged sterilized devices are ready for use at the completion of the cycle, no cool down or aeration period is required following completion of the cycle.

The V-PRO 1 Plus Low Temperature Sterilization System provides two cycle options, Lumen and Non Lumen. The sterilizer contains a 136 L welded aluminum chamber with two shelves for device loading, an onboard printer to provide cycle printouts, a cup interface where the VAPROX HC cups are loaded, a display for the graphic user interface and the components necessary to achieve the desired cycle parameters (injection cylinder, vaporizer, vacuum pump and catalytic converter). The side panels of the sterilizer are composed of stainless steel.

The V-PRO maX Low Temperature Sterilization System provides three cycle options, Lumen, Non Lumen and Flexible. The sterilizer contains a 136 L welded aluminum chamber with two shelves for device loading, an onboard printer to provide cycle printouts, a cup interface where the VAPROX HC cups are loaded, a display for the graphic user interface and the components necessary to achieve the desired cycle parameters (injection cylinder, vaporizer, vacuum pump and catalytic converter). The side panels of the sterilizer are composed of plastic.

The purpose of this pre-market notification is to modify the maximum load weight for the Non Lumen Cycle from 19.65 to 50 lbs, to add titanium diffusion-restricted areas to the indications for use of the Non Lumen Cycle, and to remove the term "reusable" from indications for use statement.

4. Intended Use

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles [Lumen Cycle, Non Lumen Cycle, and Flexible Cycle (V-PRO maX Sterilizer only)] operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' **Lumen Cycle** can sterilize:[a]

- Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: [a]
    - single channeled devices with a stainless lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length
    - dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
    - triple channeled devices with stainless steel lumens that are
        - ≥ 1.2 mm ID and ≤ 275 mm in length

- ≥ 1.8 mm ID and ≤ 310 mm in length

or

- ≥ 2.8 mm ID and ≤ 317 mm in length

[a] The validation studies for all channel/lumen configurations were conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' **Non Lumen Cycle,** the subject of this submission, can sterilize:[b]

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

[b] The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

The V-PRO maX Low Temperature Sterilization System'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 two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c]

   The flexible endoscopes 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 that is ≥ 1 mm ID and ≤ 850 mm in length

[c] The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d]

   The flexible endoscope can contain either:

   - a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
   - or two lumens with:
     - one lumen that is ≥ 1 mm ID and ≤ 990 mm in length

- and the other lumen that is ≥ 1 mm and ≤ 850 mm in length

[d] The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

The parameters for the three V-PRO Cycles are as follows:

Sterilization Cycle	Sterilant injection (g)	# of Injections	Sterilant Exposure Time (min)	Chamber Pressure Prior to Injection (Torr)	Chamber/ Vaporizer Temperature (°C)
Lumen	2.1	4	32	0.4	50/60
Non Lumen	2.1	4	12	1	50/60
Flexible	2.1	4	12	0.4	50/60

5. Summary of Nonclinical Tests

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems have the same or similar intended use and the same technological characteristics as compared to the predicate devices. Performance testing to assess and demonstrate substantial

equivalence to the predicates is summarized below.

Test	Result	Conclusion	
		V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Proposed Device)	**V-PRO 1 Plus/V-PRO maX Low Temperature Sterilization System (Predicate Devices/K131 120)**
½ Cycle Modified Total Kill Endpoint Verification	Modified total kill end point analysis was demonstrated for the Non Lumen Cycle. The standard injection weight of 2.1 g and at least one lower injection weight resulted in all sterile results within the validation load. Partial positives or all survive results were seen at lower injection weights.	PASS	PASS
½ Cycle Sterilization Verification of Cycle Claims	The Non Lumen Cycle reproducibly sterilizes non-lumened devices, mated surfaces and device tray accessories contact sites under worst case conditions in ½ Cycle	PASS	PASS
Simulated Use Test	Simulated use testing verified the ability of the Non Lumen Cycle to sterilize medical devices under worst case processing conditions.	PASS	PASS
Final Process Qualification	The Non Lumen Cycle final process qualification was successful. Manual inspection of the process parameter data confirmed that all cycle specifications were met.	PASS	PASS
Sterilizer Accessories Performance	Three lots of VERIFY® V24 Self-Contained Biological Indicator (SCBI) were reproducibly sterilized under worst case ½ cycle conditions. Three lots of SCBI process indicators (PIs) exhibited a passing color change and all SCBIs were negative for growth under worst case full cycle conditions. Three lots of VERIFY® HPU chemical indicator exhibited complete color change under worst case full cycle conditions. Test articles were effectively sterilized under worst case ½ cycle conditions when packaged in: • Vis –U-All Low Temperature Pouches or • V-PRO Sterilization Trays	PASS	PASS

6. Conclusion

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems Non Lumen Cycle has been validated to meet the established performance criteria. The results of the V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' Non Lumen Cycle verification studies demonstrate that the sterilizers perform as intended. Based on the intended uses, technological characteristics and non-clinical performance data, the subject devices (V-PRO 1 Plus and V-PRO maX) are as safe, as effective and perform at least as safely and effectively as the legally marketed predicate device (K131120), Class II (21 CFR 880.6860), product code MLR.