510(k) Summary
For

V-PRO® maX 2 Low Temperature Sterilization System, V-PRO® maX Low Temperature Sterilization System, V-PRO® 1 Plus Low Temperature Sterilization System, V-PRO® 1 Low Temperature Sterilization System

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Premarket Notification Number: K190103

1. Device Name

Trade Name:	V-PRO® maX 2 Low Temperature Sterilization System, V-PRO® maX Low Temperature Sterilization System, V-PRO® 1 Plus Low Temperature Sterilization System, V-PRO® 1 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 for V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems is the V-PRO maX Low Temperature Sterilization System, cleared most recently under **K172319**.

The claimed primary predicate device for the V-PRO® maX 2 Low Temperature Sterilization Systems is the V-PRO maX 2 Low Temperature Sterilization System, cleared most recently under **K172754**.

3. Description of Device

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

The sterilizers have one 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 uses VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). The four 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. 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 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).

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) 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 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 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 2 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 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 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
- 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).

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).

Table 5-1. Technological Characteristic Comparison between the proposed V-PRO 1, V-PRO 1 Plus and 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 – K172319)	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (K190103)
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-	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-

Feature	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (Predicate Device – K172319)	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (K190103)
	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 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).* 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) 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*	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: wo flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain either: a. A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length b. 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).* 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).* ne flexible endoscope with a light cord (if not egral to endoscope) and mat and additional n-lumened instruments.†† The flexible doscope 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*

Feature	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (Predicate Device – K172319)	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (K190103)
	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 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 • 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).*	*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 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 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).*
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 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (Predicate Device – K172319)	V-PRO 1, V-PRO 1Plus, V-PRO maX Low Temperature Sterilization System (K190103)
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

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

Table 5-2. Technological Characteristics 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/K172754)	V-PRO maX 2 Low Temperature Sterilization System (K190103)
Indications for Use	The V-PRO maX 2 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	The V-PRO maX 2 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

Feature	V-PRO maX 2 Low Temperature Sterilization System (Predicate Device/K172754)	V-PRO maX 2 Low Temperature Sterilization System (K190103)
	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 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	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 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: 2. 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

Feature	V-PRO maX 2 Low Temperature Sterilization System (Predicate Device/K172754)	V-PRO maX 2 Low Temperature Sterilization System (K190103)
	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 • 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).	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 • 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).
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 maX 2 Low Temperature Sterilization System (Predicate Device/K172754)	V-PRO maX 2 Low Temperature Sterilization System (K190103)
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 three 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 three 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 for the Lumen cycle and consequently their labeling (operator manual).

6. Summary of Non-Clinical Testing

Non-clinical performance test was performed according to the test methodology listed below. The testing demonstrated that the subject device met the acceptance criteria described in the standard/methodology.

Test	Result	Conclusion
½ Cycle Modified Total Kill Endpoint Verification	Modified total kill end point analysis was demonstrated for the sterilizer cycles. The standard injection weight of 2.1 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. Conclusions

Based on the intended use, technological characteristics and non-clinical performance data, the V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization System is as safe, as effective and performs as well or better than the legally marketed predicate device K172319, Class II (21 CFR 880.6860), product code MLR.

Based on the intended use, technological characteristics and non-clinical performance data, the V-PRO maX 2 Low Temperature Sterilization System is as safe, as effective and performs as well or better than the legally marketed predicate device K172754, Class II (21 CFR 880.6860), product code MLR.