DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 9, 2018

STERIS Corporation
Bill Brodbeck, Ph.D.
Director, Regulatory Affairs
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K172754
Trade/Device Name: V-PRO® maX 2 Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Sterilizer, Ethylene Oxide Gas
Regulatory Class: Class II
Product Code: MLR
Dated: January 9, 2018
Received: January 10, 2018

Dear Dr. Bill Brodbeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K172754

Device Name
V-PRO® maX 2 Low Temperature Sterilization System

Indications for Use *(Describe)*
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. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle and 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
- 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).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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

510(k) Summary
For

V-PRO® maX 2 Low Temperature Sterilization System

K172754

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

Contact: Bill Brodbeck
Director, Regulatory Affairs
Tel: 440-392-7690
Fax: 440-357-9198

Submission Date: February 6, 2018

1. Device Name

Trade Name:	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 Low Temperature Sterilization System, cleared most recently under **K162413**.

The V-PRO maX Low Temperature Sterilization System prior clearances include Premarket Submissions **K102330**, **K112760**, **K112813**, **K120632, K131120** and **K162413**.

A comparison between the proposed V-PRO maX 2 Low Temperature Sterilization System to the predicate device is summarized in the table below.

Feature	V-PRO maX 2 Low Temperature Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K162413)
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. **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 Fast Non Lumen Cycle can sterilize: ***	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 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

Feature	V-PRO maX 2 Low Temperature Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K162413)
	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 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 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: 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:	endoscopes, with the following configurations: [a] ○ single channeled devices with a stainless steel lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length ○ dual lumen devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length ○ 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** 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 50.0 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

Feature	V-PRO maX 2 Low Temperature Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K162413)
	▪ 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).	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: 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.
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 Sterlization System (Proposed Device)	V-PRO maX Low Temperature Sterlization System (Predicate Device/K162413)
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.	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 - 52 minutes Non Lumen Cycle - 28 minutes Flexible Cycle - 35 minutes Fast Non Lumen Cycle – 16 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. 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. The sterilant cup is read by a 2-D matrix code
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	The following accessories are available for the V-PRO maX Low Temperature Sterilization System • Self-contained biological indicator • Biological indicator challenge pack • Fast Acting Biological Indicator • Chemical indicator • Trays & Tray Accessories • Pouches • Tape

The proposed device has an intended use similar to the predicate with the differences being the addition of the Fast Non Lumen Cycle and slight modification to the text to allow conciseness and clarity. Both the predicate and proposed devices have the same technological characteristics. Although, the devices slightly differ, the provided descriptive characteristics and performance data demonstrate equivalence. Therefore, the proposed V-PRO maX 2 Low Temperature Sterilization System is substantially equivalent to the predicate device, the V-PRO maX Low Temperature Sterilization System.

3. Description of Device

The V-PRO maX 2 Low Temperature Sterilization System is a new vaporized hydrogen peroxide sterilizer model to be added to the STERIS V-PRO family of

sterilizers. The V-PRO product line currently consists of the Amsco V-PRO 1, Amsco V-PRO 1 Plus, V-PRO maX and V-PRO 60 Sterilizers.

As with the predicate device (K162413), the V-PRO maX 2 Sterilizer has three pre-programmed cycles (the Lumen Cycle, the Non Lumen Cycle and the Flexible Cycle) with a fourth added (the Fast Non Lumen Cycle). The V-PRO maX 2 Low Temperature Sterilization System is intended for terminal sterilization of cleaned, rinsed, dried and packaged reusable surgical instruments used in healthcare facilities.

The V-PRO maX 2 Sterilizer uses VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). Its 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. Intended Use

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. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle and 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 load 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
- 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. Description of Safety and Substantial Equivalence

The V-PRO maX 2 Low Temperature Sterilization System has the same intended use and different technological characteristics that do not raise different questions of safety and effectiveness as compared to the predicate device. Performance testing to assess and demonstrate substantial equivalence to the predicate is summarized below.

Test	Result	Conclusion
AOAC Sporicidal Test	All 720 carriers processed using 3 lots of EOSL sterilant were sterile.	PASS

Test	Result	Conclusion
Determination of D-value and Total Kill Endpoint	Greater than a 12 log reduction of the most resistant organism is achieved within all cycles (Lumen Cycle, Non Lumen Cycle, Flexible Cycle and Fast Non Lumen) of the V-PRO maX 2 Sterilizer.	PASS
½ Cycle Modified Total Kill Endpoint Verification	Modified total kill end point analysis was demonstrated for all four V-PRO maX 2 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
½ Cycle Sterilization Verification of Cycle Claims	• The Lumen Cycle reproducibly sterilizes single, dual and triple lumen devices under worst case conditions in ½ Cycle • The Flexible Cycle reproducibly sterilizes 1 x 990 mm flexible endoscope lumens under worst case conditions in ½ Cycle • The Non Lumen Cycle reproducibly sterilizes non-lumened devices under worst case conditions in ½ Cycle • The Fast Non Lumen Cycle reproducibly sterilizes non-lumened devices under worst case conditions in ½ Cycle	PASS
½ Cycle Verification of Mated Surfaces	Sterile efficacy was demonstrated for mated surfaces under worst case conditions	PASS
Simulated Use Test	Simulated use testing verified the ability of the V-PRO maX 2 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 maX 2 Sterilizer cycles to sterilize patient-soiled, clinically-cleaned, medical instruments.	PASS
Biocompatibility	Cytotoxicity and residue analysis of 23 materials have demonstrated biocompatibility after processing in the V-PRO 60 Sterilizer.	PASS
Medical Device Material Compatibility	Evaluation of medical devices after multiple cycles in the V-PRO maX 2 Sterilizer has demonstrated compatibility with 23 materials of construction.	PASS
Final Process Qualification	The V-PRO maX 2 Sterilizer final process qualification was successful for all four (4) sterilizer cycles.	PASS

The V-PRO maX 2 Low Temperature Sterilization System has been tested for conformity and is certified to the following standards:

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

- EN 61326-1:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device K162413, Class II (21 CFR 880.6860), product code MLR.