August 7, 2023

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

Re: K223476
Trade/Device Name: V-PRO maX 2 Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: July 12, 2023
Received: July 12, 2023

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,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
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)*
K223476

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.

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 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 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
• ≥ 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).

The Specialty 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 or one pouch with guide(s)/model(s) (with or without tray) for a total weight of 11 lbs (5 kg).
or
Patient-specific surgical guides (e.g. osteotomy, shoulder, hip, knee, spine) or anatomical models fabricated via additive manufacturing (3D printing) processes and intended for single-use during operative procedures.**
** The validation studies were conducted using a validation load consisting of pouched guide(s)/model(s) (with or without tray) for a total weight of 5 lbs (2.3 kg) 3D printed material. Devices used in validation studies were prepared in accordance with printer manufacturers' instructions for use, to include printing, curing, removal of support material and cleaning.

Material	Manufacturer	Specialty Cycle	Lumens
Surgical Guide Resin	Formlabs	F	≥3 mm ID x ≤30 mm L
BioMed Amber Resin	Formlabs	F	≥3 mm ID x ≤30 mm L
Dental LT Clear V2 Resin	Formlabs	D	≥3 mm ID x ≤30 mm L
BioMed Clear Resin	Formlabs	D	≥3 mm ID x ≤30 mm L
Biocompatible Clear MED610	Stratasys	E	≥3 mm ID x ≤20 mm L
Biocompatible Opaque MED615RGD	Stratasys	E	≥3 mm ID x ≤20 mm L
VeroGlaze™ MED620	Stratasys	E	≥3 mm ID x ≤20 mm L

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
For K223476

V-PRO® maX 2 Low Temperature Sterilization System

STERIS Corporation
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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: August 1, 2023

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 2 Low Temperature Sterilization Systems, cleared most recently under **K222093**.

Table 5-1. A comparison between the proposed V-PRO maX 2 Low Temperature Sterilization System to the predicate device

Feature	V-PRO maX 2 Low Temperature Sterlization System (Predicate Device/K222093)	V-PRO maX 2 Low Temperature Sterlization System (Proposed Device/ K223476)
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. **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 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. ‡ 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).

Feature	V-PRO maX 2 Low Temperature Sterlization System (Predicate Device/K222093)	V-PRO maX 2 Low Temperature Sterlization System (Proposed Device/ K223476)
	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) and 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 • ≥ 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).	**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) and 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 • ≥ 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).

<table>
<tr><th>Feature</th><th>V-PRO maX 2 Low Temperature Sterlization System (Predicate Device/K222093)</th><th>V-PRO maX 2 Low Temperature Sterlization System (Proposed Device/ K223476)</th></tr>
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• Time
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<tr><td>Software/ Firmware Controlled</td><td>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.</td><td>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, Fast Non Lumen or Specialty pre-programmed cycle.</td></tr>
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Feature	V-PRO maX 2 Low Temperature Sterlization System (Predicate Device/K222093)	V-PRO maX 2 Low Temperature Sterlization System (Proposed Device/ K223476)
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 Five cycles. Sterilant Cup is read by an RFID reader.
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 <u>Specialty Cycle</u> Specialty Cycle A – 1 hr. Specialty Cycle B – 2 hr. Specialty Cycle C – 4 hr. Specialty Cycle D – 8 hr. Specialty Cycle E – 16 hr. Specialty Cycle F – 21 hr.
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 V-PRO maX 2 sterilizer has the following pre-programmed cycles: the Lumen Cycle, the Non Lumen Cycle, the Flexible Cycle, the Fast Non Lumen Cycle, and the Specialty Cycle. The V-PRO Low Temperature Sterilization Systems are intended for terminal sterilization of cleaned, rinsed, dried, and packaged 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 five 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

There is no change to the intended use. The Indications for use are detailed in Table 5.1. The differences between the proposed devices and predicate are only the addition of the Specialty Cycle to the V-PRO maX 2 Sterilizer.

5. Technological Characteristics

The proposed and predicate device 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 a risk assessment of the proposed change to the predicate is summarized below.

Test	Result	Conclusion
½ Cycle (Sterilization) Efficacy	The standard injection weight of 2.1 g resulted in all sterile results within the validation load used to qualify each sterilizer cycle.	PASS
Material Compatibility	Material evaluations verified the compatibility of tested materials in the V-PRO max 2 Sterilizer's Specialty Cycle	PASS
Biocompatibility	Testing in accordance with ISO 10993-1 have demonstrated biocompatibility of identified materials after processing in three (3) consecutive cycles of the V-PRO maX 2 Sterilizer's Specialty Cycle.	PASS
Final Process Qualification	The V-PRO maX 2 Sterilizer final process qualification was successful for the Specialty Cycle.	PASS

6. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission, the V-PRO maX 2 Low Temperature Sterilization System, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K222093, Class II (21 CFR 880.6860), product code MLR.