October 29, 2026

Steris
Matthew Dobie
Senior Regulatory Affairs Specialist
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K263530
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: September 29, 2026
Received: September 29, 2026

Dear Matthew Dobie:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN A. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.10.29 13:41:49 -04'00'

Stephen Anisko
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K263530

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 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 single or dual channel lumens that are ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length.
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat, and additional 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:
o 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:
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.*
or
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.**

3D Printed Devices constructed of the following materials, and lumen if present, must be sterilized in the Specialty Cycle identified

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
MED615RGD	Stratasys	E	≥3 mm ID x ≤20 mm L
MED620	Stratasys	E	≥3 mm ID x ≤20 mm L
MED610	Stratasys	E	≥3 mm ID x ≤20 mm L

* The validation studies were conducted using a validation load consisting of single-pouched guide(s)/model(s) (with or without tray) with a total weight of 5 lbs. (2.3 kg) of 3D printed material.
** The validation studies were conducted using a validation load consisting of pouched devices (with or without tray) for a total weight of 11 lbs. (5 kg).

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary
for
K263530 V-PRO® maX 2 Low Temperature Sterilization System

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600

Contact: Matthew Dobie
Senior Regulatory Affairs Specialist
Phone: (440) 519-7844
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Submission Date: October 29, 2026

Submission Number: K263530

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 predicate device is the V-PRO maX 2 Low Temperature Sterilization System, cleared most recently under K233065. VAPROX HC Sterilant is the required sterilant used in the V-PRO Low Temperature Sterilization Systems. The comparison table below compares the predicate and proposed VAPROX HC Sterilant. There are no changes to any of the V-PRO Low Temperature Sterilization Systems.

The proposed and predicate devices are identical in all ways with the exception of the source of hydrogen peroxide.

3. **Description of Device**

VAPROX HC Sterilant is a 59% hydrogen peroxide sterilant used only the V-PRO Low Temperature Sterilization Systems (V-PRO). It was originally cleared for use in K062297 and the cup was modified in K112813. It has also been cleared as part of the various V-PRO Sterilizer models. This Premarket Notification is only for a proposed alternate source of hydrogen peroxide for use in STERIS manufacturing of VAPROX HC Sterilant; there are no modifications to any of the V-PRO Low Temperature Sterilization Systems listed below:

- V-PRO 1
- V-PRO 1 Plus
- V-PRO maX
- V-PRO maX 2
- V-PRO 60
- V-PRO s2

4. **Intended Use/Indications for Use**

This modification is related to the VAPROX HC sterilant. VAPROX HC Sterilant is intended for use in the V-PRO Low Temperature Sterilization Systems for terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. It has been validated for use in all cycles currently implemented on each of the V-PRO Low Temperature Sterilization Systems.

The V-PRO maX 2 Low Temperature Sterilization System are intended for terminal sterilization of cleaned, rinsed, dried and packaged surgical instruments used in healthcare facilities and utilizes VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). The 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.

The Indications for Use for each of the V-PRO Low Temperature Sterilization Systems are as follows:

V-PRO maX2 Low Temperature Sterilization System:

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 V-PRO maX2 Non Lumen Cycle can sterilize: ‡
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
‡ Validation testing was conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs (22.7 kg).

The V-PRO maX2 Fast Non Lumen Cycle can sterilize:*
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
** Validation testing was conducted using a validation load consisting of one pouched instrument tray for a total weight of 11 lbs (5 kg).*

The V-PRO maX2 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.
   ** Validation testing was conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).*

2. One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat, and additional non-lumened instruments.†† The flexible endoscope may contain single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length
   - Additional instruments may include non-lumened or lumened medical devices with the following configurations:
     - Single, dual or triple channel stainless steel lumen that is
     - ≥ 0.48 mm ID and ≤ 100 mm in length

   †† Validation testing was conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel

lumens. Also included in the load was a tray with additional instruments, and silicone mat for a total weight of 24 lbs (11 kg).

The V-PRO maX2 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 V-PRO maX2 Specialty Cycle can sterilize:
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.**
*** Validation testing was 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.*
or
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.*
** Validation testing was conducted using a validation load consisting of one pouched instrument tray or 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).*

3D Printed Devices constructed of the following materials, and lumen if present, must be sterilized in the Specialty Cycle identified

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

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.

Table 1. Technological comparison between the proposed and predicate devices

Feature	VAPROX HC Sterilant Predicate K233065	VAPROX HC Sterilant Proposed	Comparison
Intended Use	VAPROX HC Sterilant is intended for use in the V-PRO Low Temperature Sterilization Systems for terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities.	VAPROX HC Sterilant is intended for use in the V-PRO Low Temperature Sterilization Systems for terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities.	Identical
Active Ingredient	59% Hydrogen Peroxide (nominal)	59% Hydrogen Peroxide (nominal)	Identical
Design of Cup	Multiple use cup	Multiple use cup	Identical
Minimum Cycles per Cup	SKUs: PB007 – 15 PB011 – 15 PB012 – 4	SKUs: PB007 – 15 PB011 – 15 PB012 – 4	Identical
Form during Use	Vaporized hydrogen peroxide	Vaporized hydrogen peroxide	Identical
Sterilant Delivery	External chamber placement	External chamber placement	Identical
Sterilant Injection	Fixed dose	Fixed dose	Identical
Label Coding	SKUs: PB007 – Data matrix PB011 – RFID PB012 – RFID	SKUs: PB007 – Data matrix PB011 – RFID PB012 – RFID	Identical
Shelf Life	SKUs: PB007 – 15 months PB011 – 15 months PB012 – 6 months	SKUs: PB007 – 15 months PB011 – 15 months PB012 – 6 months	Identical

6. Summary of Non-Clinical Testing

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

Table 2. Summary of Testing

Test	Acceptance Criteria	Result	Conclusion
D-value	The proposed and predicate devices must meet D-value specifications.	D-value results for the proposed and predicate devices meet specifications.	PASS
Biocompatibility	Testing in accordance with ISO 10993-1 must demonstrate an	Testing in accordance with ISO 10993-1 demonstrated an	PASS

Test	Acceptance Criteria	Result	Conclusion
	equivalent biocompatibility profile between the proposed and predicate devices	equivalent biocompatibility profile between the proposed and predicate.	
Shelf Life	The proposed must meet specifications for each time point evaluated over shelf life.	The proposed meets specifications for each time point evaluated over shelf life.	PASS

7. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission, 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 cleared under K233065, Class II (21 CFR 880.6860), product code MLR.