October 20, 2023

Steris
Jennifer Nalepka
Manager, Regulatory Affairs
5960 Heisley Road
Mentor, Massachusetts 44060

Re: K233065
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 25, 2023
Received: September 26, 2023

Dear Jennifer Nalepka:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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 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

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control

and Plastic and Reconstructive 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)*
K233065

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
K233065 V-PRO® maX 2 Low Temperature Sterilization System

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

Contact: Jennifer Nalepka
Manager, Regulatory Affairs
Phone: (440) 392-7458
email: jennifer_nalepka@steris.com

Submission Date: October 19, 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 K223476. VAPROX HC Sterilant is the required sterilant used in the V-PRO Low Temperature Sterilization Systems. The comparison table, Table 1 in Section 5, 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 device are identical in all ways except the grade of sterilant in the predicate compared to the proposed.

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 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.

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. The most recent Premarket Notifications for each model are identified in Table 1. This Premarket Notification is only for a proposed modification to VAPROX HC; 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, which has the following 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. It has been validated for use in all cycles currently implemented on each of the V-PRO Low Temperature Sterilization Systems.

Intended Use/Indications for Use V-PRO maX 2:
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: *
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* *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:
  - 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).

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  - ≥ 0.77 mm ID and ≤ 527 mm in length
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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).*

5. Technological Characteristics Comparison

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. A comparison between the proposed and predicate devices

Feature	VAPROX HC Sterilant Predicate K223476	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 PB028 – 4	SKUs: PB007 – 15 PB011 – 15 PB012 – 4 PB028 – 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 PB028 – Data matrix	SKUs: PB007 – Data matrix PB011 – RFID PB012 – RFID PB028 – Data matrix	Identical
Shelf Life	SKUs: PB007 – 15 months PB011 – 15 months PB012 – 6 months PB028 – 6 months	SKUs: PB007 – 15 months PB011 – 15 months PB012 – 6 months PB028 – 6 months	Identical

6. Summary of Nonclinical 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	Result	Acceptance Criteria	Conclusion
D-value	The D-value for the proposed meets specifications of the predicate.	D-value of proposed formulation must meet that established for the predicate.	PASS
Biocompatibility	Testing in accordance with ISO 10993-1 have demonstrated an equivalent biocompatibility profile between the proposed and predicate.	The biocompatibility profile of the proposed formulation must be equivalent to the predicate formulation.	PASS

Test	Result	Acceptance Criteria	Conclusion
Shelf Life	The proposed meets specifications over the same shelf life as that of the predicate.	The proposed formulation must meet the same specifications as the predicate in shelf life testing: • Package appearance • Sterilant Color • Clarity • Hydrogen peroxide Concentration • Sterilant pH	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 and reference devices cleared under K223476, Class II (21 CFR 880.6860), product code MLR.