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

October 7, 2016

STERIS Corporation
Mr. Tony Piotrkowski
Senior Manager, Regulatory Affairs
5960 Heisley Road
Mentor, OH 44060

Re: K160912
Trade/Device Name: Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 9, 2016
Received: September 12, 2016

Dear Mr. Tony 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. 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 and Part 809); 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 and Part 809), 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" (21 CFR 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 yours,

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)* K160912

Device Name Sterilization Trays

Indications for Use *(Describe)*

The Sterilization Trays are used to contain medical devices for sterilization in the Lumen, Non Lumen and Flexible Cycles of the V-PRO Low Temperature Sterilization Systems. Prior to placing in the Sterilizer, the trays must either be:

- wrapped with a legally marketed sterilization wrap for use in the V-PRO Low Temperature Sterilization Systems or
- placed inside a legally marketed pouch for enclosing trays in the V-PRO Low Temperature Sterilization Systems.

The Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments.

Model Number (size LxWxH in inches)	Intended Sterilization Cycles	Intended Tray Load
VP0045 (13x4.5x2.25) VP0046 (19x4.5x2.25) VP0047 (25x4.5x2.25) VP0048 (13x7.75x2.25) VP0049 (19x7.75x2.25) VP0050 (27x7.75x4) VP0051 (12x11.75x4) VP0052 (25x11,75x4.5) VP0053 (25x14x5)	V-PRO 60 Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ○ triple lumen devices ▪ ≥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
	V-PRO 60 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	V-PRO 60 Flexible Cycle	One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length
	V-PRO 1, 1 Plus & maX Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 527 mm in length ○ triple lumen devices ▪ ≥ 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
	V-PRO 1 Plus & maX Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors.

Model Number (size LxWxH in inches)	Intended Sterilization Cycles	Intended Tray Load
VP0045 (13x4.5x2.25) VP0046 (19x4.5x2.25) VP0047 (25x4.5x2.25) VP0048 (13x7.75x2.25) VP0049 (19x7.75x2.25) VP0050 (27x7.75x4) VP0051 (12x11.75x4) VP0052 (25x11,75x4.5) VP0053 (25x14x5)	V-PRO maX Flexible Cycle	Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes 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 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 Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.

Instrument organizers are optional accessories intended to stabilize cylindrical medical instruments within the Sterilization Trays.

Model	Description	Model	Description
VP0063	3 mm - 7mm, Tall	VP0067	3 mm - 7 mm, Short
VP0064	7 mm - 11mm, Tall	VP0068	7 mm -11 mm, Short
VP0065	11 mm - 15 mm, Tall	VP0069	11 mm - 15 mm, Short
VP0066	15 mm - 19mm, Tall	VP0070	15 mm – 19 mm, Short

Sterilization mats are optional accessories intended to cushion and stabilize instruments within the Sterilization Trays.

Model	Description	Model	Description	Model	Description
VP0071	13 x 4.5	VP0074	13 x 7.75	VP0077	12 x 11.75
VP0072	19 x 4.5	VP0075	19 x 7.75	VP0078	25 x 11.75
VP0073	25 x 4.5	VP0076	27 x 7.75	VP0079	25 x 14

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
Sterilization Trays

K160912

Sponsor Facility

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

Repackager/Relabeler Facility

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Phone: (440) 392-7800
Fax No: (440) 392-7896

Contact: Tony Piotrkowski
Senior Manager, Regulatory Affairs

Telephone: (440) 392-7437
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Submission Date: September 9, 2016

1. Device Name

Trade Name:	Sterilization Trays
Common/usual Name:	Sterilization Trays, cassettes and other accessories
Classification Name:	Sterilization Wrap 21 CFR 880.6850 Class II Product Code KCT

2. Predicate Device

V-PRO Sterilization Tray K140494

3. Description of Device

The Sterilization Trays contain medical devices for sterilization in the V-PRO Low Temperature Sterilization Systems: V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Low Temperature Sterilization Systems. The trays are available in various sizes, outlined in **Table 10-1,** to accommodate the loads to be processed. The proposed trays are similar in design to the predicate V-PRO Sterilization Tray (K140494) and are composed of a base and a lid. The lid includes clamping mechanisms designed to secure the lid onto the base. There are numerous holes in the base and lid for sterilant penetration. The tray is categorized as a cassette and requires complete enclosure in a legally-marketed sterilization wrap or pouch to maintain sterility of the enclosed devices.

Table 10-1. External Dimensions of Tray Line

Model	Description	Model	Description
VP0045	13 x 4.5 x 2.25	VP0050	27 x 7.75 x 4
VP0046	19 x 4.5 x 2.25	VP0051	12 x 11.75 x 4
VP0047	25 x 4.5 x 2.25	VP0052	25 x 11.75 x 4.5
VP0048	13 x 7.75 x 2.25	VP0053	25 x 14 x 5
VP0049	19 x 7.75 x 2.25		

Optional instrument organizers are provided as accessories to the trays and allow stabilization of various cylindrical medical devices during processing. **Table 10-2** lists the organizer sizes. The organizers are either "blank" and are used to partition the tray or have a device holding portion into which the devices are inserted. At the organizer base is a flapped groove that is used to position the organizer within a Sterilization Tray.

Table 10.2. Instrument Organizer Model Numbers

Model	Description	Model	Description
VP0063	3 mm - 7mm, Tall	VP0067	3 mm - 7 mm, Short
VP0064	7 mm - 11mm, Tall	VP0068	7 mm -11 mm, Short
VP0065	11 mm - 15 mm, Tall	VP0069	11 mm - 15 mm, Short
VP0066	15 mm - 19mm, Tall	VP0070	15 mm – 19 mm, Short

Optional sterilization mats are provided as accessories to the trays. The mats, which are used to cushion and stabilize devices placed into the trays, are available in sizes as shown in **Table 10-3** to fit the nine Sterilization Trays. The mats are a diamond grid design with "fingers" that extend from each corner of the diamond and at the midpoint of each diamond side. The fingers cushion and stabilize instruments, helping to prevent the instruments from freely moving in the tray during packaging, sterilization and storage. The cushioning and stabilization qualities help protect delicate instruments placed into the trays.

Table 10-3. Sterilization Tray Model Numbers

Model	Description	Model	Description
VP0071	13 x 4.5	VP0076	27 x 7.75
VP0072	19 x 4.5	VP0077	12 x 11.75
VP0073	25 x 4.5	VP0078	25 x 11.75
VP0074	13 x 7.75	VP0079	25 x 14
VP0075	19 x 7.75		

4. Intended Use/ Indications for Use

The Sterilization Trays are used to contain medical devices for sterilization in the Lumen, Non Lumen and Flexible Cycles of the V-PRO Low Temperature Sterilization Systems. Prior to placing in the Sterilizer, the trays must either be:

- wrapped with a legally marketed sterilization wrap for use in the V-PRO Low Temperature Sterilization Systems or
- placed inside a legally marketed pouch for enclosing trays in the V-PRO Low Temperature Sterilization Systems.

The Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments.

Model Number (size LxWxH in inches)	Intended Sterilization Cycles	Intended Tray Load
VP0045 (13x4.5x2.25) VP0046 (19x4.5x2.25) VP0047 (25x4.5x2.25) VP0048 (13x7.75x2.25) VP0049 (19x7.75x2.25) VP0050 (27x7.75x4) VP0051 (12x11.75x4) VP0052 (25x11,75x4.5) VP0053 (25x14x5)	V-PRO 60 Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ○ triple lumen devices ▪ ≥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
	V-PRO 60 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	V-PRO 60 Flexible Cycle	One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length
	V-PRO 1, 1 Plus & maX Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 527 mm in length ○ triple lumen devices ▪ ≥ 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
	V-PRO 1 Plus & maX Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors.

Sterilization Trays

Model Number (size LxWxH in inches)	Intended Sterilization Cycles	Intended Tray Load
VP0045 (13x4.5x2.25) VP0046 (19x4.5x2.25) VP0047 (25x4.5x2.25) VP0048 (13x7.75x2.25) VP0049 (19x7.75x2.25) VP0050 (27x7.75x4) VP0051 (12x11.75x4) VP0052 (25x11,75x4.5) VP0053 (25x14x5)	V-PRO maX Flexible Cycle	Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes 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 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 Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.

Instrument organizers are optional accessories intended to stabilize cylindrical medical instruments within the Sterilization Trays.

Model	Description	Model	Description
VP0063	3 mm - 7mm, Tall	VP0067	3 mm - 7 mm, Short
VP0064	7 mm - 11mm, Tall	VP0068	7 mm -11 mm, Short
VP0065	11 mm - 15 mm, Tall	VP0069	11 mm - 15 mm, Short
VP0066	15 mm - 19mm, Tall	VP0070	15 mm – 19 mm, Short

Sterilization mats are optional accessories intended to cushion and stabilize instruments within the Sterilization Trays.

Model	Description	Model	Description	Model	Description
VP0071	13 x 4.5	VP0074	13 x 7.75	VP0077	12 x 11.75
VP0072	19 x 4.5	VP0075	19 x 7.75	VP0078	25 x 11.75
VP0073	25 x 4.5	VP0076	27 x 7.75	VP0079	25 x 14

5. Summary of Technical Characteristics

The sterilization trays, sterilization mats and instrument organizers are identical in composition to the claimed predicate devices. The technical characteristics are summarized in **Table 10-4**.

Table 10-4 Summary of Tray Physical Description and Technological Properties

Feature	Sterilization Tray (proposed)	V-PRO Sterilization Tray (K140494)	Comparison
Intended Use	The Sterilization Trays are used to contain medical devices for sterilization in the Lumen, Non Lumen and Flexible Cycles of the V-PRO Low Temperature Sterilization Systems. Prior to placing in the Sterilizer, the trays must either be: • wrapped with a legally marketed sterilization wrap for use in the V-PRO Low Temperature Sterilization Systems or • placed inside a legally marketed pouch for enclosing trays in the V-PRO Low Temperature Sterilization Systems. The Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments. Instrument organizers are optional accessories intended to stabilize cylindrical medical instruments within the Sterilization Trays. Sterilization mats are optional accessories intended to cushion and stabilize instruments within the Sterilization Trays.	The V-PRO Sterilization Tray is used to contain medical devices for sterilization in the Lumen, Non Lumen and Flexible Cycles of the V-PRO Low Temperature Sterilization Systems and to maintain sterility of properly processed medical devices during normal handling and storage until they are removed for use. The trays must be wrapped with a legally marketed sterilization wrap for use in the V-PRO Low Temperature Sterilization Systems prior to placing in the Sterilizer. Optional instrument organizers are accessories to the tray and are intended to allow stabilization of various cylindrical medical devices during processing. The instrument organizers attach to the V-PRO Sterilization Tray base and stabilize cylindrical medical instruments.	Adding ability to pouch trays for sterilization or to process pouched items in a wrapped or pouched tray – peroxide residual and sterilant penetration testing demonstrate safety and efficacy. Use of Vis-U-All pouches with the trays is part of separate, concurrent, submission.
Vent to Volume Ratio	All trays are the same: 0.135 in^{-1}	All trays are the same: 0.137 in^{-1}	Similar; peroxide residual and sterilant penetration testing demonstrate safety and efficacy
Tray Composition	Glass-filled polypropylene, stainless steel	Polypropylene, Noryl and stainless steel	Similar, Compatibility testing demonstrates safety and efficacy

Feature	Sterilization Tray (proposed)	V-PRO Sterilization Tray (K140494)	Comparison
Organizer Composition	Medical Grade Silicone, USP grade VI	Polypropylene	Compatibility testing demonstrates safety and efficacy
Mat Composition	Medical Grade Silicone, USP grade VI	Medical Grade Silicone, USP grade VI	Same

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 10-5** below.

Table 10-5. Summary of Non-clinical Testing

Test	Acceptance Criteria	Conclusion
Demonstration of Effective Sterilant Penetration	Worst case test article packaged in the trays shall be reproducibly sterilized under worst case ½ cycle conditions.	PASS
Package Integrity	Not applicable, Trays to be used with legally marketed sterilization wrap or pouch.	
Maintenance of Package Integrity		
Demonstration of Effective Drying and Aeration	Residual hydrogen peroxide levels shall be below acceptable levels after exposure to worst case Sterilizer Cycle conditions.	PASS
Demonstration of Effective Cleaning	Clean following automated and manual cleaning.	PASS
Demonstration of Material Compatibility	After processing through multiple worst case sterilization cycles, the trays and accessories shall retain functionality.	PASS
Demonstration of Biocompatibility	Component materials shall be non cytotoxic after exposure to worst case Sterilizer Cycle conditions.	PASS

7. Conclusion

The Sterilization Trays have met the established performance criteria. The results of the studies demonstrate that the sterilization trays and accessories perform as intended, and based on the nonclinical tests performed, the subject device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate devices, Class II (21 CFR 880.6850, Product code KCT.