STERIS®

JUL 2 5 2014

510(k) Summary
For
V-PRO Sterilization Tray

K140494

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Summary Date: July 25, 2014

1. Device Name

Trade Name:	V-PRO 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

VHP® 136 Tray (renamed V-PRO Sterilization Tray) K070769
Sterilization Mat K103226

3. Description of Device

The V-PRO Sterilization Tray is available in various sizes, 10"x 10" to 10" x 27" to accommodate the loads to be processed. The tray contains two handles that remain internalized during wrapping/processing and a lid with clamping mechanisms for securing to the tray. There are numerous holes in the tray and larger holes in the lids for sterilant penetration. The purpose of this premarket submission is to modify the trays by adding a longer tray to the existing product line (10" x 27"), to increase the vent area of the tray lid, and to extend indications for use of the tray to include the V-PRO 60 Low Temperature Sterilization System.

Optional instrument organizers are provided as accessories to the tray and are intended to allow stabilization of various cylindrical medical devices during processing. Each organizer consists of a device holding element and lock base that attaches to the V-PRO Sterilization Tray. The sizes for the device holding element range from a 5 mm diameter and 6 mm stem height to a 19 mm diameter and 25 mm stem height. For attachment to the tray, each device holding element is positioned over one of the numerous holes at the inner tray surface and pushed into a lock base located at the respective tray hole on the outer tray surface. A minimum of two, aligned organizers should be used for each device that requires stabilization. Once the device is placed into the organizers, it is secured by each organizer's twist lock. The organizers are identical to those previously cleared under K070769.

Sterilization mats are provided as optional accessories to the tray and are identical to those previously cleared under K103226 for use in V-PRO Low Temperature Sterilizers' Lumen, Non Lumen and Flexible Cycles. A larger mat sized to fit into the new 10" x 27" tray has been added to the existing product line. The sterilization mats are intended to cushion and stabilize devices placed into the V-PRO.

Sterilization Trays. The mats are available in sizes to fit the five V-PRO 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 V-PRO Sterilization Trays.

4. Intended Use

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. 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. The V-PRO sterilization Tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed medical instruments.

Proposed Tray Model	Intended Sterilization Cycles	Intended Tray Load
VP0040 VP0041 VP0042 VP0043 VP0044	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: o single or dual lumen devices ▪ 0.77 mm ID and 410 mm in length o 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: o single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length

Proposed Tray Model	Intended Sterilization Cycles	Intended Tray Load
VP0040 VP0041 VP0042 VP0043 VP0044	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: o single or dual lumen devices ▪ 0.77 mm ID and 527 mm in length o 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.
	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.

Optional instrument organizers are accessories to the trays 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.

Optional sterilization mats are accessories to the trays and are intended to be used in conjunction with the V-PRO Sterilization Trays to cushion and stabilize instruments within the trays..

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 **Tables 5-1** and **5-2** below.

Table 5-1 Summary of Tray Physical Description and Technological Properties

Feature	V-PRO Sterilization Tray (proposed)	V-PRO Sterilization Tray (K070769)	Comparison
Intended Use	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.	The V-PRO Sterilization Tray is used to contain devices for sterilization in the Amsco V-PRO 1 Low Temperature Sterilizer 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, FDA cleared sterilization wrap for use in the V-PRO 1 Low Temperature Sterilizer prior to placement in the Sterilizer. The V-PRO Sterilization Tray can be used with V-PRO Instrument Organizers to allow stabilization of various cylindrical medical devices during processing. The Instrument Organizers attach to the V-PRO Sterilization Tray bottom and stabilize cylindrical medical instruments.	Data is presented in this submission to demonstrate safety and effectiveness in the V-PRO 60 Low Temperature Sterilization System.
Material Compatibility	Compatible with VHP Sterilization.	Compatible with VHP Sterilization.	Same materials of composition

Feature	V-PRO Sterilization Tray (proposed)	V-PRO Sterilization Tray (K070769)	Comparison
Sterilant Penetration	Effective penetration of the VAPROX HC Sterilant into double wrapped trays under worst case conditions during the V-PRO 60 Sterilizer's processing cycles was demonstrated. Verification of effective penetration to sterilize longest /narrowest stainless steel lumen for the V-PRO 1/1 Plus/maX Lumen Cycle is also provided.	Effective penetration of the VAPROX HC Sterilant into double wrapped trays under worst case conditions during the V-PRO 1 Sterilizer's processing cycle was demonstrated.	Data is presented in this submission to demonstrate effective sterilant penetration in the V-PRO 60 Low Temperature Sterilization System.
Toxicological Properties	Materials of construction retain biocompatibility.	Materials of construction retain biocompatibility	Same
Microbial Barrier Properties	To be used with legally marketed sterilization wrap.	To be used with legally marketed sterilization wrap.	Same
Vent to Volume Ratio	All trays are the same: 0.137 in^{-1}	Minimum: 0.049 in^{-1} Maximum: 0.054 in^{-1}	Proposed device has a higher vent to volume ratio due to a modification of the lid vent area, allowing easier sterilant penetration than the predicate.
Tray Composition	Polypropylene, Noryl and stainless steel	Polypropylene, Noryl and stainless steel	Same
Organizer Composition	Polypropylene	Polypropylene	Same

Table 5-2 Summary of Mat Physical Description and Technological Properties

Feature	Sterilization Mat (proposed)	Sterilization Mat (K103226)	Comparison
Intended Use	The sterilization mats are optional accessories intended to be used exclusively in V-PRO Sterilization Trays to cushion and stabilize instruments during sterilization in the Amsco V-PRO Low Temperature Sterilization Systems.	The sterilization mats are intended to be used in conjunction with the V-PRO™ Sterilization Trays (K070769) to cushion and stabilize instruments during sterilization in the Amsco® V-PRO Low Temperature Sterilization Systems.	New intended use point out that the mats are optional accessories to the V-PRO Sterilization Tray
Composition	USP grade VI Silicone	USP grade VI Silicone	Same
Toxicological Properties	Materials of construction retain biocompatibility.	Materials of construction retain biocompatibility	Same

Feature	Sterilization Mat (proposed)	Sterilization Mat (K103226)	Comparison
Sterilant Penetration	Effective penetration of the VAPROX HC Sterilant into double wrapped trays under worst case conditions during the V-PRO 60 Sterilizer's processing cycles was demonstrated.	Effective penetration of the VAPROX HC Sterilant into double wrapped trays under worst case conditions during the V-PRO 1 Sterilizer's processing cycle was demonstrated.	Data is presented in this submission to demonstrate effective sterilant penetration in the V-PRO Sterilization Tray with the sterilization mat in the V-PRO 60 Low Temperature Sterilization System.
Material Compatibility	Compatible with VHP Sterilization.	Compatible with VHP Sterilization.	Same materials of composition

Models and sizes of V-PRO Sterilization Trays, Sterilization Mats and Instrument Organizers are included in **Table 5-3**. The 10" x 27" sizes of trays and mats are new for this submission. All other sizes are identical to the predicates VHP® 136 Tray (K070769) and Sterilization Mat (K103226).

Table 5-3. V-PRO Sterilization Tray and Mat Sizes

Tray Product Code	Tray Base Size (inches)*	Mat Size (inches)*	Mat Product Code
VP0040	10 x 10	10 x 10	VP0030
VP0041	10 x 14	10 x 14	VP0031
VP0042	10 x 17	10 x 17	VP0032
VP0043	10 x 21	10 x 21	VP0033
**VP0044	10 x 27	10 x 27	VP0034**

*Sizes are approximated for ease of reference.
** The 10" x 27" size is being added in this submission

Models and sizes of V-PRO Sterilization Tray Instrument Organizers are included in **Table 5-4**. The sizes and model numbers are identical to the predicate VHP® 136 Tray (K070769).

Table 5-4. Instrument Organizers Available Sizes

Stem Length (mm)	Diameter* (mm)	Part Number	Stem Length (mm)	Diameter* (mm)	Part Number
6	5	99101	6	14	99110
13	5	99102	13	14	99111
25	5	99103	25	14	99112
6	9	99104	6	17	99113
13	9	99105	13	17	99114
25	9	99106	25	17	99115
6	11	99107	6	19	99116
13	11	99108	13	19	99117
25	11	99109	25	19	99118
Lock Base		99120			

*Sizes are approximated for ease of reference.

6. Summary of Nonclinical Tests

The sterilization trays, sterilization mats and instrument organizers are identical in composition and have the same or similar intended use as compared to the predicate device. The only substantial difference is the claim of using the subject device with the V-PRO 60 Low Temperature Sterilization System (subject of a separate, concurrent submission). Therefore, performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-5** below.

Table 5-5. Instrument Organizers Available Sizes

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
Demonstration of Biocompatibility	Component materials shall be non cytotoxic after exposure to worst case V-PRO 60 Sterilizer Cycle conditions.	PASS
	Residual hydrogen peroxide levels shall be below acceptable levels after exposure to worst case V-PRO 60 Sterilizer Cycle conditions.	PASS
Demonstration of Sterilant Compatibility	After processing through multiple worst case sterilization cycles, the trays and accessories shall retain functionality.	PASS

7. Conclusion

The V-PRO Sterilization Trays have been validated to meet the established performance criteria. The results of the verification 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.

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

July 25, 2014

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

Re: K140494
Trade/Device Name: V-PRO Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap Containers, Trays, Cassettes and other accessories
Regulatory Class: II
Product Code: KCT
Dated: June 20, 2014
Received: June 23, 2014

Dear Mr. 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); 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140494

Device Name: **V-PRO Sterilization Tray**

Indications For Use:

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. 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. The V-PRO Sterilization Tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed medical instruments.

Proposed Tray Model	Intended Sterilization Cycles	Intended Tray Load
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	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: o single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length

Proposed Tray Model	Intended Sterilization Cycles	Intended Tray Load
VP0040 VP0041 VP0042 VP0043 VP0044	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: o single or dual lumen devices ▪ 0.77 mm ID and 527 mm in length o 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.
	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.

Optional instrument organizers are accessories to the trays 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.

Optional sterilization mats are accessories to the trays and are intended to be used in conjunction with the V-PRO Sterilization Trays to cushion and stabilize instruments within the trays.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300055864, cn=Elizabeth F. Claverie -S
Date: 2014.07.25 09:52:20 -04'00'