

STERIS®

FEB 18 2011



**510(k) Summary
For
Sterilization Mat use in V-PRO Sterilizers**

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Summary Date: January 17, 2010

1. Device Name

Trade Name: Sterilization Mats
Common/usual Name: Sterilization Mats
Classification Name: Sterilization Tray Accessory
21 CFR 880.6850
Product Code KCT

2. Predicate Device

APTIMAX Instrument Tray, Instrument Tray Holder, and Instrument Tray Mat (K013003)

3. Description of Device

The sterilization mats are used to cushion and stabilize devices placed into the V-PRO Sterilization Trays (K070769). The mats are available in sizes to fit the four 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 Trays.

The mats are designed to allow sterilization of cleaned and dried medical devices during the V-PRO Lumen (K062297), Non Lumen (K083097) and Flexible (K102330) Cycles in the V-PRO Sterilizers.

4. Intended Use

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.

5. Summary of Nonclinical Tests

The sterilization mats have the same or similar intended use and the same technological characteristics as compared to the predicate device. Performance testing to demonstrate substantial equivalence to the predicate is summarized in the table below.

**K103226/S001 STERIS Response to 12/23/10 Request for Additional Information
Sterilization Mats for use in V-PRO Sterilizers**

Test	Acceptance Criteria	Conclusion
Demonstration of Effective Sterilant Penetration	Worst case test article for each of the three V-PRO Sterilization Cycles must be reproducibly sterilized under worst case ½ cycle conditions.	PASS
Demonstration of Biocompatibility	Silicone shall be non cytotoxic after exposure to worst case V-PRO Cycle conditions.	PASS
	Residual hydrogen peroxide levels must be below acceptable levels after exposure to worst case V-PRO Cycle conditions.	PASS
Demonstration of Sterilant and Cleaning Agent Compatibility	After processing through multiple cleaning and worst case sterilization cycles, the mats must not display any incompatibilities with VAPROX HC sterilant and typical cleaning agents.	PASS
Cleaning Evaluating	The mats must be easy to clean using either a manual or an automated process.	PASS

6. Conclusion

The sterilization mats have been validated to meet the established performance criteria. The results of the verification studies demonstrate that the sterilization mats perform as intended and the proposed device is substantially equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert F. Sullivan
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FEB 18 2011

Re: K103226
Trade/Device Name: Sterilization Mats
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: January 17, 2011
Received: January 18, 2011

Dear Mr. Sullivan:

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.

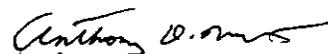
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



Anthony D. Watson, B.S., M.S., M.B. A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103226

Device Name: Sterilization Mats

Indications For Use:

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.

The sterilization mats have been validated for use in the three pre-programmed V-PRO sterilization cycles [Lumen Cycle (the only cycle of the V-PRO 1 Sterilizer), Non Lumen Cycle, and Flexible Cycle]. The critical parameters for each of these cycles are listed below.

Sterilization Cycle	Sterilant Injection (g)	# of Injections	Sterilant Exposure Time (min)	Chamber Pressure Prior to Injection (Torr)	Chamber/Vaporizer Temperature (°C)
Lumen	2.1	4	32	0.4	50/60
Non Lumen	2.1	4	12	1	50/60
Flexible	2.1	4	12	0.4	50/60

The **Lumen Cycle**, cleared under K062297, can sterilize:^a

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless steel lumen with:
 - an inside diameter of 1 mm or larger and a length of 125 mm or shorter
 - an inside diameter of 2 mm or larger and a length of 250 mm or shorter
 - an inside diameter of 3 mm or larger and a length of 400 mm or shorter

^a The validation testing for all lumen sizes was conducted using a maximum of twenty (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 (containing two mats and 20 instrument organizers) and two pouches for a total weight of 19.65 lbs.

The **Non Lumen Cycle**, cleared under K083097, can sterilize:^b

Non-lumened instruments including non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

^b The validation studies were conducted using a validation load consisting of two instrument trays containing two mats, and 20 instrument organizers and two pouches for a total weight of 19.65 lbs.

**K103226/S001 STERIS Response to 12/23/10 Request for Additional Information
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The Flexible Cycle, subject of K102330, can sterilize:

Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.^e

The flexible endoscopes may contain either:

- a single Teflon lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
- or two Teflon lumens with:
 - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
 - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

^c The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat, 20 instrument organizers 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 including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.^d

The flexible endoscope can contain either:

- a single Teflon lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
- or two Teflon lumens with:
 - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
 - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

^d The validation studies were conducted with a flexible endoscope in a tray with silicone mat, 20 instrument organizers and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray (containing a mat and 20 instrument organizers) and one pouch for a total load weight of 24.0 lbs.

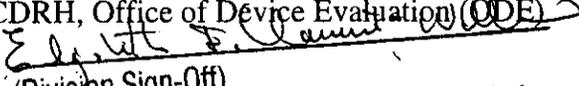
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Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(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) 

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103226
