STERIS®

OCT 5 2007

K070769

510(k) Summary
For
V-PRO™ Sterilization Tray
and
Instrument Organizers

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Submission Date: March 20, 2007

1. Device Name

Trade Name:	**V-PRO™ Sterilization Tray and Instrument Organizers.**
Common/usual Name:	Sterilization Trays, Cassettes and other Accessories.
Classification Name:	General Hospital and Personal Use Devices (21 CFR 880.6850).
Product Code:	KCT

2. Predicate Devices

The **V-PRO™ Sterilization Tray** is substantially equivalent to legally marketed existing devices as indicated in Table 5-1

Table 5-1. V-PRO™ 136 Tray Predicate Devices information

Device Name	Conmed Linvatec Instrument Sterilization Tray	Olympus Sterilization Trays	Aptimax Instrument Tray
K#	K052992	K033222	K013003
SE Date	10/16/06	08/02/04	08/28/02

STERIS Corporation performed qualification testing to support the suitability of the V-PRO™ Sterilization Tray in the Amsco® V-PRO™ 1 Low Temperature Sterilization System (K062297). The qualification testing data is included in this submission.

The V-PRO™ Sterilization Tray as well as the predicate devices are intended to hold, transport and store sterilized medical devices. They are supplied in a variety of sizes and configurations to accommodate various medical instruments. The design and material composition of the V-PRO™ Sterilization Tray and the indicated predicate devices allow diffusion of the sterilant around the contents when used with approved sterilization wrap.

3. Description of Device

The V-PRO™ Sterilization Tray is available in various sizes, 10"x 10" to 10" x 21" to accommodate the loads to be processed. The tray contains two handles that remain internalized during wrapping/processing and a lid with two clamping mechanisms for securing to the tray. There are numerous 0.01" diameter holes in the lid and tray for sterilant penetration. The tray is categorized as a cassette and requires complete enclosure in a legally marketed, FDA cleared sterilization wrap

for use in the Amsco® V-PRO™ 1 Low Temperature Sterilizer to maintain sterility of the devices.

The tray can contain medical device organizers to allow stabilization of various cylindrical medical devices during processing. Each organizer consists of a device holding element and lock base that attach 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 requiring stabilization. Once the device is placed into the organizers, it is secured by each organizer's twist lock.

4. Intended Use

The V-PRO™ Sterilization Tray is used to contain reusable medical 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 Amsco® V-PRO™ 1 Low Temperature Sterilizer prior to placing 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 medical device organizers attach to the V-PRO™ Sterilization Tray bottom and stabilize cylindrical medical instruments.

Tables 5-2 and 5-3 list the trays and instrument organizers included in this submission.

Table 5-2. V-PRO™ Sterilization Tray available sizes for use in the Amsco® V-PRO™ 1 Low Temperature Sterilizer.

Tray Type (inches)	Recommended Max Load (lbs)*	Recommended Maximum Instrument Organizers
21 x 10	9.13	20
17 x 10	6.47	20
14 x 10	5.16	16
10 x 10	4.48	10

* Includes weight of the tray

Table 5-3. V-PRO™ Instrument Organizers for use with the V-PRO™ Sterilization Tray

Diameter (mm)	Stem Height (mm)
5	6
	13
	25
9	6
	13
	25
11	6
	13
	25
14	6
	13
	25
17	6
	13
	25
19	6
	13
	25

5. Description of Safety and Substantial Equivalence

The V-PRO™ Sterilization Tray qualified by STERIS Corporation for use in the Amsco® V-PRO™ 1 Low Temperature Sterilizer as a medical device has been shown to be safe and effective.

This device qualified by STERIS Corporation for use in the Amsco® V-PRO™ 1 Low Temperature Sterilizer has the same intended use and characteristics, including the availability of different sizes as the predicate devices. Refer to Section 12 for detailed information regarding Substantial Equivalence.

6. Performance Specifications and Design Requirements

The V-PRO™ Sterilization Tray must demonstrate sterilization of devices when wrapped, material compatibility with the various healthcare processing chemistries and Vaprox HC Sterilant, cleaning efficacy, and the inability to emit harmful substances after processing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jack Scoville
Fellow Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

OCT 5 ˇ 2007

Re: K070769
Trade/Device Name: V-PRO™ Sterilization Tray and Instrument Organizers
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: September 7, 2007
Received: September 10, 2007

Dear Mr. Scoville:

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.

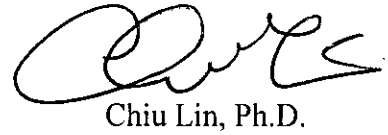
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): K070769

Device Name: V-PRO™ Sterilization Tray and Instrument Organizers.

Indications For Use:

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 Amsco® V-PRO™ 1 Low Temperature Sterilizer prior to placing 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.

Tables 1 and 2 list the trays and instrument organizers included in this submission.

Table 1. V-PRO™ Sterilization Tray available sizes for use in the Amsco® V-PRO™ 1 Low Temperature Sterilizer.

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Table 2. V-PRO™ Instrument Organizers for use with the V-PRO™ Sterilization Tray

Diameter (mm)	Stem Height (mm)
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	13
	25
9	6
	13
	25
11	6
	13
	25

Diameter (mm)	Stem Height (mm)
14	6
	13
	25
17	6
	13
	25
19	6
	13
	25

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070769