AUG 0 3 2009

STERIS®

510(k) Summary
For
Amsco V-PRO 1 Plus Low Temperature Sterilization System

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Summary Date: July 31, 2009

1. Device Name

Trade Name:	Amsco V-PRO 1 Plus Low Temperature Sterilization System
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
FDA classification number:	21 CFR 880.6860
Product Code:	80 MLR.

2. Predicate Device

- Amsco V-PRO 1 Low Temperature Sterilization System: K062297.

3. Overview

The purpose of this 510(k) is to obtain premarket clearance for the Amsco V-PRO 1 Plus Low Temperature Sterilization System. The V-PRO 1 Plus has an added pre-programmed Non Lumen Cycle as compared to the Amsco V-PRO 1 Low Temperature Sterilization System. This cycle is intended for sterilization of non lumened surgical instruments.

4. Description of Device

The Amsco V-PRO 1 Plus Low Temperature Sterilizer is a self-contained stand-alone device using vaporized hydrogen peroxide. This device is intended for use in terminal sterilization of cleaned, rinsed and dried, reusable medical devices used in healthcare facilities. The sterilizer operates at low pressure and low temperature and is therefore suitable for processing medical devices sensitive to heat and moisture.

5. Intended Use

The Amsco V-PRO 1 Plus Low Temperature Sterilization System, with VAPROX HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles, the Lumen and the Non Lumen Cycles, operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The Amsco V-PRO 1 Plus Low Temperature Sterilizer System's **Lumen Cycle** was cleared under K062297. The Lumen Cycle can sterilize*

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

* 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 and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO 1 Plus Low Temperature Sterilization System's **Non Lumen Cycle** can sterilize**:

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

** The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

6. Description of Safety and Substantial Equivalence

The proposed and predicate devices have the same intended use. The difference between the proposed and predicate device is limited to the addition of a Non Lumen sterilization cycle. The difference does not raise any new issues of safety and efficacy.

7. Performance Testing Summary

Performance Testing – Bench

Effectiveness
Effectiveness of sterilizer function and exposure time recommendations was demonstrated by complete kill of biological indicators and by verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} probability of survival. STERIS validates its sterilization cycles using recommended practices, standards and guidelines developed by independent organizations such as the Association for the Advancement of Medical Instrumentation (AAMI).

The Amsco V-PRO 1 Plus Low Temperature Sterilization System has been validated to meet the requirements of FDA Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities, 1993 and Addendum to the Sterilizer guidance document, 1995.

The results of the Amsco V-PRO 1 Plus Low Temperature Sterilization System verification studies demonstrate that the sterilizer performs as intended. The results are summarized as follows:

Safety
STERIS sterilizers including the Amsco V-PRO 1 Plus Low Temperature Sterilization System have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Amsco V-PRO 1 Plus Low Temperature Sterilization System complies with the following requirements:

- Underwriters Laboratory (UL) Electrical Safety Code 61010-1 certified by Intertek Testing Services (ITS).
- Canadian Standards Association (CSA) Standard C22.2 No. 1010-1 as certified by Intertek Testing Services.
- American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels.

Hazards – Failure of Performance
Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident. To avoid failure, the user must ensure that the materials, instruments and devices to be sterilized are thoroughly cleaned and dried, the manufacturer's instructions for use are followed, the cycle to be used for each type of sterilizer load has been validated, the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

8. Conclusion

The Amsco V-PRO 1 Plus Low Temperature Sterilization System's Non Lumen Cycle has been validated to meet the established performance criteria. The results of the Amsco V-PRO 1 Plus Low Temperature Sterilization System verification studies demonstrate that the Non Lumen Cycle performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 0 3 2009

Re: K083097
Trade/Device Name: Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System
Regulation Number: 21 CFR 880. 6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: July 22, 2009
Received: July 23, 2009

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 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" (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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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): **K083097**

Device Name: **Amsco V-PRO 1 Plus Low Temperature Sterilization System**

Indications for Use:

The Amsco V-PRO 1 Plus Low Temperature Sterilization System, with VAPROX HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles; the Lumen and the Non Lumen Cycles operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The Amsco V-PRO 1 Plus Low Temperature Sterilizer System's (Lumen Cycle) was cleared under (K062297) can sterilize *:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless steel lumen with:
  - o an inside diameter of 1 mm or larger and a length of a 125 mm or shorter
  - o an insider diameter of 2 mm or larger and a length of 250 mm or shorter
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The Amsco V-PRO 1 Plus Low Temperature Sterilization System's (Non Lumen Cycle) the subject of this (K083097) can sterilize**:

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

** The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles T. Murphy MD

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

510(k) Number: K083097