K020747

MAY 17 2002

510(k) SUMMARY

Submitter Information
Lori Haller, Manager, Regulatory Affairs
STERIS Corporation
2424 West 23rd Street
Erie, Pennsylvania 16506
(814) 870-8559
Date Summary Prepared: May 8, 2002

Introduction

The Amsco Century Medium Steam Sterilizer 26" x 26" is a Class II medical device as defined by 21 CFR 880.6880. This sterilizer is intended for the terminal sterilization of non-porous and porous, heat and moisture-stabile materials used in healthcare facilities. The Amsco Century Medium Steam Sterilizer 26" x 26" is substantially equivalent with the predicate device Amsco Century Medium Steam Sterilizer, K010865, cleared May 31, 2001.

The Amsco Century Medium *Prevacuum* Steam Sterilizer 26" x 26" is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-A):

Table 1-A

CYCLES	STERILIZE TEMPERATURE	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack.
Prevac	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table 2 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
Liquid	250°F (121°C)	45 minutes	N/A	*Refer to Table 3 for recommended quantities.*

The Amsco Century Medium *Steam Flush Pressure-Pulse* (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-B):

Table 1-B

CYCLES	STERILIZE TEMPERATURE	STERILIZE TIME	DRY TIME	RECOMMENDED LOADS
SFPP	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
Wrap/SFPP	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each, Non-Porous Goods only. *Refer to Table 2 for recommended quantities.*

Prevac	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table 2 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*

The following table lists STERIS's recommended loads by sterilizer size:

Table 2

STERILIZER SIZE	WRAPPED INSTRUMENT TRAYS	FABRIC PACKS
26" x 26" x 39"	4	12
26" x 26" x 49"	6	16
26" x 26" x 61"	8	20

The following table is a guideline for the liquid cycle processing:

Table 3

NUMBER OF CONTAINERS	VOLUME OF LIQUID IN ONE CONTAINER	MINIMUM RECOMMENDED STERILIZE TIME AT 250°F (121°C)
3	1000 mL	45 minutes

Effectiveness

Effectiveness of sterilizer function and exposure time recommendations is 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). Prior to release, the Amsco Century Medium Steam Sterilizer 26" x 26" will be validated to meet the requirements of ANSI/AAMI ST8, Third Edition, January, 1994.

The results of the Amsco Century Medium Steam Sterilizer 26" x 26" verification studies demonstrate that the sterilizer performs as intended. The results are summarized as follows:

- All SFPP cycles verified using the fabric test pack, described in Section 5.5.1.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.1 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, a moisture retention of less than 3% increase in presterilization test pack weight, and no evidence of wet spots.
- All WRAP/SFPP cycles verified using full load instrument trays, described in 5.5.3.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.3 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.

- All GRAVITY cycles verified using the fabric test pack, described in Section 5.5.1.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.1 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, a moisture retention of less than 3% increase in presterilization test pack weight, and no evidence of wet spots.
- All PREVAC cycles verified using the fabric test pack, described in Section 5.5.1.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.1 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, a moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.
- All PREVAC cycles verified using full load instrument trays, described in 5.5.3.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.3 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.
- All LIQUID cycles verified using three 1,000 ml flasks, described in Section 5.5.2.1 of the ANSI/AAMI-ST8, were qualified according to Section 5.5.2 of ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, water loss not exceeding 50 ml, and automatic sealing of the flask closure.
- The DART cycle verified using the Bowie-Dick Test Pack, as described in 5.6.1.1 of the ANSI/AAMI-ST8, was qualified according to Section 5.6.1 of the ANSI/AAMI-ST8, and demonstrated a uniform color change throughout the test sheet.
- The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document "*Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (5/29/98).*"

Safety

STERIS sterilizers including the Amsco Century Medium Steam Sterilizer 26" x 26" have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Amsco Century Medium Steam Sterilizer 26" x 26" complies with the following requirements:

- Underwriters Laboratory (UL) Electromedical Code 3101 as 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, 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.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incidence of sterilizer malfunction or sterilization process failure is relatively rare. Further, there are no known reports in the literature of patient infections that have resulted from steam sterilizer failures. The technology designed into STERIS steam sterilizers including the Amsco Century Medium Steam Sterilizer 26" x 26" provides microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

User Information

STERIS conducts in-house training and has developed a series of user training videos that provide helpful information about the appropriate use of steam sterilizers. STERIS further provides information to the user that is intended to ensure safe and effective use of steam sterilization in its detailed Operator Manual and other labeling. STERIS also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2003

Ms. Lori Haller
Manager, Regulatory Affairs
Steris Corporation
2424 West 23rd Street
Erie, Pennsylvania 16506

Re: K020747
Trade/Device Name: Amsco Century Medium Sterilizer 26
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: March 5, 2002
Received: March 7, 2002

Dear Ms. Haller:

This letter corrects our substantially equivalent letter of May 17, 2002 regarding the product code.

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.

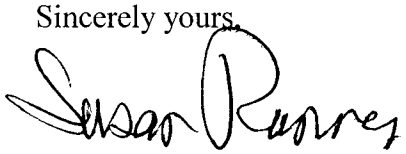
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim 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 STATEMENT
DEVICE NAME:
AMSCO CENTURY MEDIUM STEAM STERILIZER 26" X 26"

INDICATIONS FOR USE:
The Amsco Century Medium Steam Sterilizer 26" x 26" is designed for sterilization of heat and moisture-stabile materials used in healthcare facilities and is available in two configurations:

- *Prevacuum* – is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP)* – is equipped with SFPP, WRAP/SFPP, Prevacuum, Gravity, Leak Test and DART (Bowie-Dick) cycles.

The Amsco Century Medium *Prevacuum* Sterilizer 26" x 26" is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-A):

Table 1-A

CYCLES	STERILIZE TEMPERATURE	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack.
Prevac	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table 2 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
Liquid	250°F (121°C)	45 minutes	N/A	*Refer to Table 3 for recommended quantities.*

The Amsco Century Medium *Steam Flush Pressure-Pulse* (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1-B):

Table 1-B

CYCLES	STERILIZE TEMPERATURE	STERILIZE TIME	DRY TIME	RECOMMENDED LOADS
SFPP	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
Wrap/SFPP	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Non-Porous Goods only. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, maximum weight of 17 lbs (7.7 kg) each. Fabric Packs. *Refer to Table 2 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*

The following table lists STERIS recommended loads by sterilizer size:

Table 2

STERILIZER SIZE	WRAPPED INSTRUMENT TRAYS	FABRIC PACKS
26" x 26" x 39"	4	12
26" x 26" x 49"	6	16
26" x 26" x 61"	8	20

The following table is the guideline for liquid cycle processing:

Table 3

NUMBER OF CONTAINERS	VOLUME OF LIQUID IN ONE CONTAINER	MINIMUM RECOMMENDED STERILIZE TIME AT 250°F (121°C)
3	1000 mL	45 minutes

The Amsco Century Medium Steam Sterilizer 26" x 26" is offered in the following configurations:

- 26" x 26" x 39" (660 mm x 660 mm x 991 mm)
- 26" x 26" x 49" (660 mm x 660 mm x 1245 mm)
- 26" x 26" x 61" (660 mm x 660 mm x 1520 mm)

(Please Do Not Write Below This Line – Continue on Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use _____
(Per 21 CFR 801.109)

Over-The-Counter Use _____
(Optional Format 1-2-96)

John Lerlh

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020747