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JUN 1 1998

# A 510(k) SUMMARY PERTAINING TO THE SAFETY AND EFFECTIVENESS OF THE EAGLE CENTURY STEAM STERILIZER

## Submitter Information

STERIS Corporation  
Raymond Ursick  
Senior Director  
Regulatory Affairs and Quality Systems  
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Date Summary Prepared: March 5, 1998

## Introduction

The AMSCO brand Eagle Century Steam Sterilizer is a Class II medical device as defined by 21 CFR §880.6880. The Eagle Century Steam Sterilizer is a sliding door sterilizer, offered in either a prevacuum or gravity configuration, intended for the terminal sterilization of heat and moisture-stabile materials.

The Eagle Century Steam Sterilizer is offered for sale with the following factory-set sterilization cycles and cycle values:

### PREVACUUM CONFIGURATION\*

CYCLES	STERILIZE TEMP.	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
FLASH	270°F (132°C)	3 minutes	1 minute	Unwrapped Instrument Tray with a Single Instrument
FLASH	270°F (132°C)	10 minutes	1 minute	Unwrapped Instrument Tray with non-porous multiple instruments (maximum weight of 17lbs)
EXPRESS	270°F (132°C)	4 minutes	3 minutes	Single Wrapped Instrument Tray with a single instrument. Non-porous goods only.
PREVAC	270°F (132°C)	4 minutes	20 minutes*	Up to two double wrapped instrument trays (maximum weight of lbs. each). Up to six fabric packs.

\*Five minutes dry time can be used for processing a single fabric pack.

Also offered with the Prevacuum configuration are the Leak Test Cycle that provides verification of door seal and piping system integrity, and the Daily Air Removal Test (DART) Cycle that provides verification of effective removal of residual air in the chamber and load during testing when combined with a DART or Bowie-Dick test pack.

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**GRAVITY CONFIGURATION**

CYCLES	STERILIZE TEMP.	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
FLASH	270°F (132°C)	3 minutes	1 minute	Unwrapped Instrument tray with a single instrument
FLASH	270°F (132°C)	10 minutes	1 minute	Unwrapped Instrument Tray with non-porous multiple instruments (maximum weight of 17 lbs.)
GRAVITY	270°F (132°C)	15 minutes	30 minutes	Up to two double wrapped instrument trays (maximum weight of 17lbs. each)
GRAVITY*	250°F (132°C)	30 minutes	15 minutes	Fabric Packs

\*A 270°F (132°C) cycle adjusted to 25 minute Sterilize Time can be used for processing Fabric Packs.

**Effectiveness**

Efficacy of sterilizer function and exposure time recommendations are ultimately shown by showing complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of less than 10<sup>-6</sup> (probability of less than one chance out of one million of a non-sterile indicator). STERIS validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI).

The results of the Eagle Century Validation demonstrate that the sterilizer performs as intended and are summarized as follows:

- ◆ Validation Studies for Compliance to AAMI-ST8<sup>1</sup>. This standard establishes the minimum construction and performance requirements for hospital sterilizers that use saturated steam as the sterilizing agent and have a volume greater than 2 cubic feet. The Eagle Century Steam Sterilizer cycles validated per AAMI-ST8 are the 250°F Gravity, 270°F Prevac and the DART test.
- ◆ Validation Studies for Compliance to AAMI-ST37<sup>2</sup>. This recommended practice covers flash sterilization in health care facilities and includes guidelines for sterilization processing procedures. The Eagle Century Steam Sterilizer cycles validated per AAMI-ST37 are the 270°F Flash and the 270°F Express.
- ◆ Validation Studies for Century with Electric Steam Generator. The customer has the choice to operate the Eagle Century on house steam, an independently purchased steam generator or a generator supplied by STERIS. STERIS conducted testing of the Century with the Electric Steam Generator to ensure that the generator recommended

<sup>1</sup>Association for the Advancement of Medical Instrumentation, "Hospital Steam Sterilizers", ANSI/AAMI-ST8-1994 (revision of ANSI/AAMI-ST8-1988).

<sup>2</sup>Association for the Advancement of Medical Instrumentation, "Flash Sterilization: Steam Sterilization of patient care items for immediate use", ANSI/AAMI-ST37-1996, (Revision of ANSI/AAMI-ST37-1992).

would provide sufficient efficiency to perform sterilization cycles. The Eagle Century Steam Sterilizer cycles validated with the Electric Steam Generator are the 270°F Prevac, 270°F Gravity and the 250°F Liquid.

- ◆ Validation Studies for Century for Liquid Cycle Efficacy. The Eagle Century Steam Sterilizer optional Liquid Cycle was validated to ensure that 100ml, 1000ml and 2000ml liquid loads with vented self-sealing closures processed properly.

### **Safety**

AMSCO brand sterilizers including the Eagle Century Steam Sterilizers have been designed, constructed and tested to minimally meet the safety and performance requirements of various national safety codes and standards. The Eagle Century Steam Sterilizer complies with the following requirements:

1. Underwriters Laboratory (UL) Electromedical Code 544 as certified by ETL Testing Laboratories, Inc.;
2. Canadian Standards Association (CSA) Standard C22.2 No. 125 or 151;
3. American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels;
4. American Society of Mechanical Engineers (ASME), Section I, Part PMB for power boilers;
5. California Seismic Pre-Approval; and
6. National Fire Protection Association Standard 99.

A Reliability Analysis and Failure Modes and Effects and Criticality Analysis has been conducted on the Eagle Century Steam Sterilizer's electrical system, mechanical system and piping system as well.

### **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 the materials, instruments and devices to be sterilized are thoroughly cleaned, that the manufacturer's instructions for use are followed, that the cycle to be used for each type of sterilizer load has been validated, that the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and that 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 considering the widespread use of steam sterilizers. Further, there are no known reports in the literature of patient infections that have resulted from steam sterilizer failure. The technology designed in AMSCO brand steam sterilizers including the Eagle Century 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.

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### **User Information**

STERIS conducts in-house user 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's 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 1 1998

Mr. Raymond Ursick  
Senior Director  
Regulatory Affairs and Quality Systems  
STERIS Corporation  
2424 West 23<sup>rd</sup> Street  
Erie, Pennsylvania 16506

Re: K964332  
Trade Name: Eagle Century Steam Sterilizer  
Regulatory Class: II  
Product Code: FLE  
Dated: March 12, 1998  
Received: March 13, 1998

Dear Mr. Ursick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531

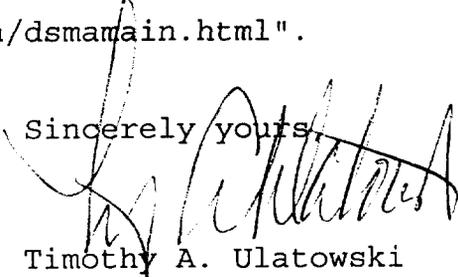
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsma.htm>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE**DEVICE NAME: EAGLE CENTURY STEAM STERILIZER****INDICATIONS FOR USE**

The STERIS Eagle Century Steam Sterilizer is designed for efficient, sterilization of non-porous and porous, heat and moisture-stable materials used in healthcare facilities. The Eagle Century Steam Sterilizer is available in the following configurations:

16" x 16" x 26" Single Door Gravity  
 16" x 16" x 26" Double Door Gravity  
 20" x 20" x 38" Single Door Gravity  
 20" x 20" x 38" Double Door Gravity

16" x 16" x 26" Single Door Prevacuum  
 16" x 16" x 26" Double Door Prevacuum  
 20" x 20" x 38" Single Door Prevacuum  
 20" x 20" x 38" Double Door Prevacuum

The Eagle Century Steam Sterilizer is equipped with the following factory-programmed set sterilization cycles and cycle values:

**Prevacuum Configuration**

CYCLES	RECOMMENDED LOADS	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
FLASH	Unwrapped Instrument tray with a single instrument	270°F (132°C)	3 minutes	1 minute
FLASH	Unwrapped instrument tray with non-porous multiple instruments, maximum weight 17lbs	270°F (132°C)	10 minutes	1 minute
EXPRESS	Single wrapped instrument tray with a single instrument. Non-porous goods only.	270°F (132°C)	4 minutes	3 minutes
PREVAC	Up to two double wrapped instrument trays, maximum weight 17lbs. Up to six fabric packs.	270°F (132°C)	4 minutes	20 minutes <sup>1</sup>

<sup>1</sup>Five minute Dry Time can be used for processing a single fabric pack.

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**GRAVITY CONFIGURATION**

CYCLES	RECOMMENDED LOAD	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
FLASH	Unwrapped Instrument tray with a single instrument.	270°F (132°C)	3 minutes	1 minute
FLASH	Unwrapped Instrument tray with non-porous multiple instruments, maximum weight 17lbs	270°F (132°C)	10 minutes	1 minute
GRAVITY	Up to two double wrapped instrument trays, maximum weight 17lbs	270°F (132°C)	15 minutes	30 minutes
GRAVITY	Fabric Packs	250°F (121°C)	30 minutes <sup>2</sup>	15 minutes

<sup>2</sup>A 270°F (132°C) cycle adjusted to 25 minute Sterilize Time can be used for processing fabric packs.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

George A. Miller for *Chin S. Lin PhD*  
 (Division Sign-Off)  
 Division of Dental, Infection Control,  
 and General Hospital Devices  
 510(k) Number K964332