K980014

MAY 15 1998

# A 510(k) SUMMARY PERTAINING TO THE SAFETY AND EFFECTIVENESS OF THE SYSTEM 2S STEAM STERILIZER

**Submitter Information.**
STERIS
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Date Summary Prepared: December 2, 1997

**Introduction.**
Moist heat in the form of saturated steam under pressure is the oldest, safest and most dependable form of sterilization. Steam sterilization is universally recognized as the method of choice, except when high temperatures, pressures and/or moist heat would damage or degrade items to be sterilized. Steam sterilizers in a wide variety of sizes are used in hospitals, clinics, clinical and research laboratories, and industry. Uses include sterilization of reusable medical devices such as surgical instruments, gowns and drapes; sterilization of sterile, single-use medical devices such as syringes and catheters; decontamination of potentially infectious waste generated during surgery or in research; sterilization of other materials, instruments and goods used in biotechnology and pharmaceutical houses, and in other applications whenever biological containment and infection control are essential.

The System 2S Steam Sterilizer is a Class II medical device as defined by 21 CFR Part 880.6880. The System 2S Steam Sterilizer is a sliding door sterilizer intended for the terminal sterilization of surgical instruments, various hospital utensils and other surgical materials and supplies to be used for human diagnostic or therapeutic procedures.

STERIS's manufacturing facility for the System 2S Steam Sterilizer is located in Erie, Pennsylvania and is registered with and regulated by the FDA. STERIS's quality assurance program is inspected by the FDA to assure that the requirements of Quality System Regulations are met. The Erie manufacturing facility is certified to the ISO 9001 Quality System Standard.

The System 2S Steam Sterilizer cycle descriptions are as follows:

1. FLASH Cycle is provided for quick turnaround processing of nonporous goods (e.g. dropped instruments) at 270°F (132°C) for 3 minutes sterilize and 1 minute dry;

2. GRAVITY Cycle is provided for the sterilization of heat and moisture stabile goods at 250°F (121°C) for 30 minutes sterilize and 15 minutes dry;

3. PREVAC Cycle is provided for the sterilization of heat and moisture stabile goods at 270°F (132°C) for 4 minutes sterilize and 30 minutes dry;

4. EXPRESS Cycle is offered for rapid processing of single-wrapped instrument trays at 270°F (132°C) for 4 minutes sterilize and 3 minutes dry;

5. DART (Bowie-Dick Test) Cycle is provided for verification of effective removal of residual air in the chamber and load during testing. This cycle is pre-programmed and fixed; and

6. LEAK Test Cycle is provided for verification of door seal and piping system integrity and is pre-programmed and fixed.

**Effectiveness.**
Under controlled conditions of temperature and pressure, steam is capable of killing all forms of sporulating and vegetative bacteria, viruses, fungi, yeast and bacterial and fungal endospores. It has been well established that *Bacillus stearothermophilus* in the form of spores is the Most Resistant Organism (MRO) to steam. Thus, during the development, qualification testing and validation of STERIS steam sterilizers, *B. stearothermophilus* spores are used in order to ensure a worst-case test of the steam sterilizer's efficacy in killing all forms of microbial and viral contamination.

Efficacy of sterilizer function and exposure time recommendations are ultimately demonstrated by showing complete kill of biological indicators and documenting an appropriate safety factor or sterility assurance level of less than $10^{-6}$ (probability of less than one chance out of one million of an non-sterile indicator). STERIS qualifies its recommended sterilization cycles through the application of rigorous performance standards and recommended practices developed by various independent organizations that have specified worst-case loads. Biological indicators used in qualification studies were in compliance with the Association for the Advancement of Medical Instrumentation (AAMI) standard for biological indicators (AAMI ST19).

The System 2S Steam Sterilizer will meet the applicable requirements of the following performance standards:
1. AAMI-ST8; and
2. AAMI-ST37.

**Safety.**
STERIS sterilizers have been designed, constructed and tested to minimally meet and typically exceed the minimum safety and performance requirements of various national codes and standards. Before release to market, STERIS sterilizers are tested and certified by independent testing agents to the

following requirements:

1. Underwriters Laboratory (UL) Electromedical Code 3101-1 (IEC 1010-1) as certified by ETL Testing Laboratories, Inc.;
2. Canadian Standards Association (CSA) Standard C22.2 No. 1010.1-92;
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. CRN Pressure Vessel Code.

The following reliability and endurance studies were also conducted:

1. A Failure Modes Effect Analysis has been conducted on the System 2S Steam Sterilizer's Electrical System, Mechanical System and Piping System.

**Hazards - Failure of Performance.**
Failure of the sterilization process can lead to incidents of ***cross contamination,*** the transmission of potentially infectious organisms from an infected person to another who was not otherwise infected prior to the incident.

**To avoid failure, the operator 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 characterized, validated and selected, that the sterilizer has been maintained in accordance with the manufacturer's recommended maintenance schedule and is operating properly, and that each sterilizer load is monitored with available biological and/or chemical sterilization process indicators.**

Today, there are thousands of steam sterilizers in daily use in hospitals throughout the United States, running several million cycles each year. Despite widespread use, 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 failure. Although the ability to prove that nosocomial infections result from failure of the sterilization process or a malfunction of the sterilizer is at best difficult, the technology designed into today's AMSCO sterilizers provides numerous built-in 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.**
Finally, STERIS conducts in-house customer training and has developed a series of user training videos that provide helpful information about the appropriate use of steam sterilizers. Through its careful attention to detail in instructions for use and other labeling, STERIS further provides information to the user that is intended to ensure safe and effective use of steam sterilization. Numerous recommended practice documents have been developed by AAMI and AORN to give guidance in techniques that are intended to reduce the risks of cross-contamination. The use and periodic review of, as well as adherence to these materials, give further assurance of the safe and effective use of steam sterilization equipment in the hospital.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 1998

Mr. Raymond Ursick
Director Regulatory Affairs and Quality Systems
Steris Corporation
2424 West 23rd Street
Erie, Pennsylvania 16514

Re: K980014
Trade Name: The System 2S Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: March 24, 1998
Received: March 25, 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 (Premarket 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 premarket notification submission does not affect any obligation you might have under sections 531

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/dsmamain.html".

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

**DEVICE NAME:**

**SYSTEM 2S STEAM STERILIZER**

**INDICATIONS FOR USE:**

The System 2S Steam Sterilizer is designed for efficient, point-of-use sterilization of non-porous and porous, heat and moisture-stabile materials used in outpatient surgery, ambulatory care and urgent care centers. The System 2S Steam Sterilizer is available in one configuration: Prevacuum 16"diameter x 26"length chamber size.

The System 2S Steam Sterilizer is equipped with the following factory-programmed set sterilization cycles and cycle values:

| CYCLES | RECOMMENDED LOAD | STERILIZE TEMP. | STERILIZE TIME | DRY TIME |
|---|---|---|---|---|
| **FLASH** | Unwrapped Instrument Tray with single instrument | 270°F (132°C) | 3 minutes | 1 minute |
| **GRAVITY*** | Fabric Pack | 250°F (121°C) | 30 minutes | 15 minutes |
| **PREVAC**** | Double Wrapped Instrument Tray | 270°F (132°C) | 4 minutes | 30 minutes |
| **EXPRESS** | Single Wrapped Instrument Tray with single instrument | 270°F (132°C) | 4 minutes | 3 minutes |

*250°F Cycle can be adjusted from factory-set value of 15 minutes dry time to 30 minutes dry time for instrument trays.
**270°F Cycle can be adjusted from factory-set value of 30 minutes dry time to 5 minutes dry time for single fabric pack.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

Chiu S. Lin
(Division Sign-Off) (Optional Format 1-2-96)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980014