JAN 20 1999

K 982332

A 510(k) SUMMARY PERTAINING TO THE SAFETY AND EFFECTIVENESS OF THE STERIS TEN SIXTEEN STEAM STERILIZER

Submitter Information.
Raymond Ursick
Senior Director, Regulatory Affairs and Quality Systems
5960 Heisley Road
Mentor, Ohio 44060
(440) 354-2600 Phone
Date Summary Prepared: June 26, 1998

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, pressure 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, doctors' and dentists' offices, clinical and research laboratories and industry. Uses include sterilization of reusable medical devices such as surgical instruments, gowns and drapes; sterilization of single-use medical devices such as syringes and catheters; decontamination of potentially infectious waste generated during surgery or research; sterilization of other materials, instruments and goods used in biotechnology and pharmaceutical houses, and in other applications whenever biological contamination and infection control are essential.

The STERIS Ten Sixteen Steam Sterilizer is a Class II medical device as defined by 21 CFR §880.6880. The Ten Sixteen is a tabletop steam sterilizer designed to sterilize heat and moisture-stabile materials used in hospital, dental or veterinary environments. The STERIS Ten Sixteen Tabletop Steam Sterilizer is available in a 10" x 16" inch chamber configuration.

STERIS's manufacturing facility for the STERIS Ten Sixteen Steam Sterilizer is located in Erie, Pennsylvania and is registered with and regulated by the FDA. STERIS's Erie facility is inspected by the FDA to assure that the requirements of Quality System Regulation are met. The Erie manufacturing facility is certified to the ISO 9001 Quality System Standard and the EN Medical Device Directive.

The STERIS Ten Sixteen Steam Sterilizer cycle descriptions are as follows:

CYCLES	RECOMMENDED LOAD	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
UNWRAPPED	Unwrapped Instrument tray with a single instrument (No lumens and no dental handpieces).	270°F (132°C)	3 minutes	0 minute
WRAPPED	Wrapped instrument pack. Paper-peel Pouches. (No lumens and no dental handpieces).	270°F (132°C)	10 minutes	45 minutes
LIQUID	Vented borosilicate glass containers (500ml or smaller).	250°F (121°C)	40 minutes	10 minutes (Cool Time)
PACKED	Fabric packs.	250°F (121°C)	30 minutes	30 minutes

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 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 a 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. The STERIS Ten Sixteen Steam Sterilizer meet the applicable requirements of the AAMI-ST55 "Tabletop Steam Sterilizers" performance standard. The STERIS Ten Sixteen Unwrapped Cycle meets the applicable requirements of AAMI-ST37 standard for flash sterilization. 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).

Safety. STERIS sterilizers have been designed, constructed and tested to meet the 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) 544 as certified by ETL Testing Laboratories, Inc.;
2. American Society of Mechanical Engineers (ASME), Section VII, Division 1; and
3. Canadian Standards Association (CSA) C22.2 No. 125 as certified by ETL Testing Laboratories, Inc.

A Failure Modes Effect Criticality Analysis was also conducted on the STERIS Ten Sixteen Steam Sterilizer's electrical, mechanical 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 following:

1. **That the materials, instruments and devices to be sterilized are thoroughly cleaned and decontaminated;**
2. **That the manufacturer's instructions for use are followed;**
3. **That the operator must select the validated cycle applicable for the load;**
4. **That the sterilizer has been maintained in accordance with the manufacturer's recommended maintenance schedule and is operating properly; and**
5. **That each sterilizer load is monitored with available biological and chemical sterilization process indicators.**

Today there are thousands of steam sterilizers in daily use in hospitals and other healthcare environments throughout the United States running several million cycles per year. Despite its 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 in today's STERIS 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. 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 assistance of the safe and effective use of steam sterilization equipment in healthcare environments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

Mr. Raymond Ursick
Senior Director
Regulatory Affairs and Quality Systems
Steris® Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: K982332
Trade Name: STERIS Ten Sixteen Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: October 21, 1998
Received: October 22, 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/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:

STERIS TEN SIXTEEN TABLETOP STEAM STERILIZER

INDICATIONS FOR USE:

The STERIS Ten Sixteen is a tabletop steam sterilizer designed to sterilize heat and moisture- stabile materials used in hospital, dental or veterinary environments. The STERIS Ten Sixteen Tabletop Steam Sterilizer is available in a 10" x 16" inch chamber configuration.

The STERIS Ten Sixteen Tabletop Steam Sterilizer is equipped with the following factory-programmed set sterilization cycles and cycle values:

CYCLES	RECOMMENDED LOAD	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
UNWRAPPED	Unwrapped Instrument tray with a single instrument (No lumens and no dental handpieces).	270°F (132°C)	3 minutes	0 minute
WRAPPED	Wrapped instrument pack: one pack, maximum weight 1300 g (2.87 lbs). Paper-peel Pouches: maximum 5 pouches, one instrument per pack, total maximum weight 500 g (1.1 lb). (No lumens and no dental handpieces).	270°F (132°C)	10 minutes	45 minutes
LIQUID	Vented Borosilicate glass containers (500ml or smaller).	250°F (121°C)	40 minutes	10 minutes (Cool Time)
PACKED	Fabric pack(s): maximum weight 1050 g (2.32 lbs).	250°F (121°C)	30 minutes	30 minutes

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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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982332