K021223

JUN 2 6 2002

510(k) SUMMARY

Submitter Information.

Hans Stadler
SAUTER AG
Head of product development
Zelgstrasse 8
CH-8583 Sulgen/ Switzerland
+41 71 644 85 97
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Introduction

The Belimed Steam Sterilizer TOP 5000 is a Class II medical device as defined by 21 CFR §880.6880.
The Belimed Steam Sterilizer TOP 5000 is substantially equivalent to the predicate devices, the Amsco Century Medium Steam Sterilizer, K0110865 and Amsco Steam Sterilizer K964332.
The Belimed Steam Sterilizer TOP 5000 is intended for the terminal sterilization of heat and moisture-stable materials in healthcare facilities.
The Belimed Steam Sterilizer TOP 5000 is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1)

Table 1: Factory programmed sterilization cycles

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
PREVAC 270° F (132°C)	270° F (132°C)	4 minutes	20 minutes	Double-wrapped Instrument Trays, max. weight of 17 lbs (7.7 kg) each. Fabric packs. *Refer to Table 2 for recommended quantities.*
PREVAC 270° F (132°C)	270° F (132°C)	4 minutes	5 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
LIQUID 250° F (121°C)	250° F (121°C)	45 minutes	-	*Refer to Table 3 for Guidelines*
EXPRESS 270° F (132°C)	270° F (132°C)	4 minutes	3 minutes	Single Wrapped Instrument Tray with non porous single instrument
FLASH 270° F (132°C)	270° F (132°C)	3 minutes	1 minute	Unwrapped Instrument Tray with a single Instrument
FLASH 270° F (132°C)	270° F (132°C)	10 minutes	1 minute	Unwrapped Instrument Tray with non porous multiple instruments (max. weight of 17 lbs)

The following table (Table 2) is SAUTER's recommended loads by sterilizer chamber size:

Table 2 : Recommended Loads

Sterilizer Chamber Size (mm)	Wrapped Instrument Trays 20"x10" max. 17lb each	Fabric Packs 11"x11"x9" max. 6.6lb each	Fabric Packs 23"x11"x11" max. 17lb each
26"x 42.5"x 41" (660 x 1080 x 1040)	9	18	9
26"x 42.5"x 55" (660 x 1080 x 1400)	12	30	12
26"x 42.5"x 67" (660 x 1080 x 1700)	15	36	15
26"x 42.5"x 79" (660 x 1080 x 2000)	18	42	18
26"x 48.5"x 43" (660 x 1230 x 1100)	9	18	9
26"x 48.5"x 55" (660 x 1230 x 1400)	12	30	12
26"x 48.5"x 67" (660 x 1230 x 1700)	15	36	15
26"x 48.5"x 79" (660 x 1230 x 2000)	18	42	18

The following table (Table 3) is SAUTER AG's Guidelines for liquid cycle processing:

Table 3: Guidelines for liquid 250°F cycle processing

Sterilizer Chamber Size (mm)	Volume of Liquid in One Container	Number of containers
26"x 42.5"x 41" (660 x 1080 x 1040)	1000 ml	126
26"x 42.5"x 55" (660 x 1080 x 1400)	1000 ml	168
26"x 42.5"x 67" (660 x 1080 x 1700)	1000 ml	210
26"x 42.5"x 79" (660 x 1080 x 2000)	1000 ml	252
26"x 48.5"x 43" (660 x 1230 x 1100)	1000 ml	126
26"x 48.5"x 55" (660 x 1230 x 1400)	1000 ml	168
26"x 48.5"x 67" (660 x 1230 x 1700)	1000 ml	210
26"x 48.5"x 79" (660 x 1230 x 2000)	1000 ml	252

Effectiveness

Efficacy of sterilizer function and exposure time recommendations ate ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} reduction. SAUTER AG 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). Prior to release, the Belimed Steam Sterilizer TOP 5000 will be validated to meet the requirements of AAMI/ANSI-ST8, Third Edition, January 1994.

The results of the Belimed Steam Sterilizer TOP 5000 verification studies demonstrate that the sterilizer performs as intended and are summarized as follows:

- All PREVAC cycles verified using the fabric test pack, as described in Section 5.5.1 AAMI/ANSI-ST8 were qualified according to section 5.5.1 AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F0 of at least 12 by ½ cycle, a moisture retention of less than 3% increase in pre-sterilization test pack weight, and exhibited no wet spots.
- All PREVAC cycles verified using full load instruments trays were qualified according to section 5.5.3 of AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F0 of at least 12 by ½ cycle, a moisture retention of less than 20% increase in pre-sterilization weight of the towel, and exhibited no wet spots on the outer wrapper.
- All FLASH cycles verified using the unwrapped instrument tray were qualified according to section 7.7.3 AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F0 of at least 12 by ½ cycle and exhibited no wet spots.
- All LIQUID cycles verified using three 1'000 ml flasks, as described in section 5.5.2.1 of AAMI/ANSI-ST8, were qualified according to section 5.5.2 of AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F0 of at least 12 by ½ cycle, a water loss not exceeding 50 ml, and automatic sealing of the flask closure. A temperature of 121°C was achieved and maintained in the center of the liquid for at least 12 minutes.
- The BD cycle was verified using the Bowie-Dick Test Pack were qualified according to section 5.6 of AAMI/ANSI-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 Pre-market Submissions for Software Contained in Medical Devices (5/29/98)"*.

Safety

SAUTER AG sterilizers including the Belimed Steam Sterilizer TOP 5000 have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Belimed Steam Sterilizer TOP 5000 will comply with the following requirements:

1. Underwriter Laboratory (UL) Code 3101-1
2. Canadian Standards Association (CSA) Standard C22.2 No. 1010-1 (IEC1010-1)

3. American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels

Hazards-Failure of Performances

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's manufacturer's 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 incident of sterilizer malfunction or sterilization process failure is relatively rare considering the wide spread use of steam sterilizers. Further, there are no known reports in the literature of patient infection that have resulted from steam sterilizer failure. The technology designed in Belimed Steam Sterilizer TOP 5000 provides microprocessor controller safeguards that aborts the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

User information

SAUTER AG provides information to the user that is intended to insure safe and effective use of steam sterilization in its detailed Operator's Manual and other labeling. SAUTER AG 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

JUN 26 2002

Sauter AG
C/O Mr. Mark Job
Responsible Third Party Official
TUV America, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K021223
Trade/Device Name: Belimed Steam Sterilizer, Model Top 5000
Regulation Number: 880.6880
Regulation Name: Stream Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: May 10, 2002
Received: June 12, 2002

Dear Mr. Job:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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 STATEMENT
DEVICE NAME: BELIMED STEAM STERILIZER TOP 5000

INDICATIONS FOR USE:

The Belimed Steam Sterilizer TOP 5000 is designed for sterilization of non porous and porous heat and moisture-stable materials used in healthcare facilities.

The Belimed Steam Sterilizer TOP 5000 is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1)

Table 1: Factory programmed Sterilization Cycles

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LIQUID 250° F (121°C)	250° F (121°C)	45 minutes	0 minute	*Refer to Table 3 for Guidelines*
EXPRESS 270° F (132°C)	270° F (132°C)	4 minutes	3 minutes	Single Wrapped Instrument Tray with non porous single instrument
FLASH 270° F (132°C)	270° F (132°C)	3 minutes	1 minute	Unwrapped Instrument Tray with a single Instrument
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The Belimed Steam Sterilizer TOP 5000 is offered in the following medium-size configurations:

26"x 42.5"x 41" (660 mm x 1080 mm x 1040 mm)	Single Door, Prevacuum
26"x 42.5"x 41" (660 mm x 1080 mm x 1040 mm)	Double Door, Prevacuum
26"x 42.5"x 55" (660 mm x 1080 mm x 1400mm)	Single Door, Prevacuum
26"x 42.5"x 55" (660 mm x 1080 mm x 1400mm)	Double Door, Prevacuum
26"x 42.5"x 67" (660 mm x 1080 mm x 1700mm)	Single Door, Prevacuum
26"x 42.5"x 67" (660 mm x 1080 mm x 1700mm)	Double Door, Prevacuum
26"x 42.5"x 79" (660 mm x 1080 mm x 2000mm)	Single Door, Prevacuum
26"x 42.5"x 79" (660 mm x 1080 mm x 2000mm)	Double Door, Prevacuum
26"x 48.5"x 43" (660 mm x 1230 mm x 1100mm)	Single Door, Floor Flush Design, Prevacuum
26"x 48.5"x 43" (660 mm x 1230 mm x 1100mm)	Double Door, Floor Flush Design, Prevacuum
26"x 48.5"x 55" (660 mm x 1230 mm x 1400mm)	Single Door, Floor Flush Design, Prevacuum
26"x 48.5"x 55" (660 mm x 1230 mm x 1400mm)	Double Door, Floor Flush Design, Prevacuum
26"x 48.5"x 67" (660 mm x 1230 mm x 1700mm)	Single Door, Floor Flush Design, Prevacuum
26"x 48.5"x 67" (660 mm x 1230 mm x 1700mm)	Double Door, Floor Flush Design, Prevacuum
26"x 48.5"x 79" (660 mm x 1230 mm x 2000mm)	Single Door, Floor Flush Design, Prevacuum
26"x 48.5"x 79" (660 mm x 1230 mm x 2000mm)	Double Door, Floor Flush Design, Prevacuum

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K02/223