SEP 23 2009

510 (k) Summary K090339

Date:	September 22, 2009
Submitters' Name/Address:	Belimed, Inc. (as Belimed Sauter AG's US Agent) 2284 Clements Ferry Road Charleston, SC 29492
Contact Person:	Chris Mannarino Product Engineer Belimed, Inc. Phone (843) 216-7424 Fax (843) 216-7707 e-mail: Chris.Mannarino@Belimed.us
Trade Name:	Belimed Steam Sterilizer Top 5000 Series 8, 6-0-12.
Classification:	Steam Sterilizer – Class II, as listed per 21 CFR 880.6880
Predicate Device:	Steam Sterilizer TOP 5000, Series 8, cleared under 510(k) K033538.

Device Description:

The Belimed Steam Sterilizer TOP 5000 Series 8 is intended for use in hospital and health care facilities.

Comparison to the Predicate Device:

The Belimed Steam Sterilizer TOP 5000 Series 8 is physically and functionally the same as the predicate device, and uses the same technology, materials, and software as the predicate device cleared under 510 (k) K033538. The only difference is the load claim for wrapped instrument trays. The predicate device has a maximum load capacity of (8) 17lb wrapped instrument trays, and the new claim has a maximum load capacity of (12) 17lb wrapped instrument trays.

Indications for Use:

The Belimed Steam Sterilizer TOP 5000, Series 8, model 6-0-12 is designed for sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities.

The Belimed Steam Sterilizer TOP 5000 Series 8, model 6-0-12, is equipped with the following factory-programmed Sterilization cycles and values (Tables 1-3).

Cycles	Sterilize Temp	Sterilize Time (minutes)	Dry Time (minutes)	Recommended Load
Prevac 270°F (132°C)	270°F (132°C)	4	30	Double-wrapped instrument trays, max. weight of 17 lbs (7.7kg) each. Fabric packs. Refer to table 2 for recommended quantities.
Prevac 270°F (132°C)	270°F (132°C)	4	5	Fabric packs
Liquid 250°F (121°C)	250°F (121°C)	45	0	Liquids not intended for direct patient contact. Refer to table 3 for guidelines.
Express 270°F (132°C)	270°F (132°C)	4	3	Single-wrapped instrument tray with non-porous single instrument
Flash 270°F (132°C)	270°F (132°C)	3	1	Unwrapped instrument tray with a single instrument
Flash 270°F (132°C)	270°F (132°C)	10	1	Unwrapped instrument tray with non-porous multiple instruments (max weight of 17lbs).

Table 1: Factory programmed Sterilization Cycles

Note on table 1: Factory set dry time is recommended minimum. Extended dry time may be required depending on local conditions.

The following table (Table 2) is Belimed Sauter AG's recommended load for the Series 8, Models 6-0-12 VS1 and 6-0-12 VS2.

Model Single door Double door	Sterilizer Chamber Size	Fabric packs, 11"x11"x 9", max. 6.6lbs each.	Wrapped Instrument Trays, 20"x 10", max. 17lbs each	Fabric packs, 23"x11"x11", max 17lbs each.
6-0-12 VS1 6-0-12 VS2	26" x 26" x 51.5" (660 x 660 x 1300)mm	16	12*	8

Table 2: Recommended Loads.

* The use of twelve (12) Instrument trays was validated using only rigid surgical and simulated instruments.

The following table (Table 3) is Belimed Sauter AG's guidelines for liquid cycle processing for Series 8, Models 6-0-12 VS1 and 6-0-12 VS2.

Model Single door Double door	Sterilizer Chamber Size	Volume of liquid in One Container	Number of Containers
6-0-12 VS1 6-0-12 VS2	26" x 26" x 51.5" (660 x 660 x 1300)mm	1000ml	88

Table 3, Guidelines for liquid 250°F cycle processing

The Belimed Steam Sterilizer TOP 5000 Series 8 is offered in the following size configurations:

26" x 26" x 51.5" (660mm x 660mm x 1300mm) Single door, Prevacuum
26" x 26" x 51.5" (660mm x 660mm x 1300mm) Double door, Prevacuum

Effectiveness:

Efficacy of sterilizer function and exposure time recommendations are 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. Belimed Sauter AG validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations, such as the Association for the Advancement of Medical Instrumentation (AAMI). Prior to release, the Belimed Steam Sterilizer TOP 5000 were validated to meet the requirements of AAMI/ANSI-ST8:2001.

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 fabric test packs as described in Section 5.5.2 of AAMI/ANSI-ST8:2001, and were qualified according to section 5.5.2.5 of AAMI ST8-2001. 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 instrument trays were qualified according to section 5.5.4 of ANSI/AAMI-ST8:2001. 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 test pack weight, and exhibited no wet spots on the outer wrapper.*
- All Flash cycles verified using the unwrapped instrument tray were qualified according to section 5.5.5.1 AAMI/ANSI-ST8:2001 and AAMI/ANSI ST36:1996 section 7.7.3. 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 were verified using three 1000 ml flasks, as described in section 5.5.3 of AAMI/ANSI ST8:2001, and were qualified according to section 5.5.3.5. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time to temperature sufficient to produce an F0 of at least 12 by ½ cycle, a water loss not exceeding 50ml, and an 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.
- A BD cycle was verified using the Bowie-Dick Test Pack and was qualified according to section 5.6 of AAMI/ANSI-ST-8, and demonstrated a uniform color change throughout the test sheet.
- The software validation for the cycle operation was performed according to the 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:

Belimed Sauter AG sterilizers including the Belimed Steam Sterilizer TOP 5000 Series 8 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 Series 8 complies with the following requirements:

1. Underwriters Laboratory (UL) Standard UL61010A-1:2002 and UL 610010A-2-0041:2002
2. Canadian Standards Association (CSA) Standard C22.2 No 1010-1 (IEC61010-1:2001)
3. American Society of Mechanical Engineers (ASME) Section VIII, Division I for unfired pressure vessels: 2001.

Hazards-Failure of Performance

Failure of the sterilization process can lead to incidence of cross contamination and 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, that the manufacturers 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 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 US. The incident of sterilizer malfunction or sterilizer process failure is relatively rare considering the wide spread use of steam sterilizers. The technology designed in the Belimed Steam Sterilizer TOP 5000, Series 8 provides microprocessor controlled safeguards that aborts a cycle and gives appropriate alerts and warnings to the operator when required conditions have not been met or a malfunction has occurred.

User Information

Belimed Sauter AG provides information to the user that is intended to insure safe and effective use of steam sterilization in its Operators Manuals and other labeling. Belimed 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 23 2009

Belimed Sauter AG
C/O Mr. Christopher P. Mannarino
Product Engineer
Belimed Incorporated
2284 Clements Ferry Road
Charleston, South Carolina 29492

Re: K090339
Trade/Device Name: Belimed Steam Sterilizer TOP 5000
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: August 31, 2009
Received: September 9, 2009

Dear Mr. Mannarino:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/Reporta Problem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K090339

Device Name: **Belimed Steam Sterilizer TOP 5000**

Indications for Use:

The Belimed Steam Sterilizer TOP 5000, Series 8, model 6-0-12 is designed for sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities.

The Belimed Steam Sterilizer TOP 5000 Series 8, model 6-0-12, is equipped with the following factory-programmed Sterilization cycles and values (Tables 1-3).

Prescription Use _____ AND/OR Over The Counter Use x OTC
(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090339

Cycles	Sterilize Temp	Sterilize Time (minutes)	Dry Time (minutes)	Recommended Load
Prevac 270°F (132°C)	270°F (132°C)	4	30	Double-wrapped instrument trays, max. weight of 17 lbs (7.7kg) each. Fabric packs. Refer to table 2 for recommended quantities.
Prevac 270°F (132°C)	270°F (132°C)	4	5	Fabric packs
Liquid 250°F (121°C)	250°F (121°C)	45	0	Liquids not intended for direct patient contact. Refer to table 3 for guidelines.
Express 270°F (132°C)	270°F (132°C)	4	3	Single-wrapped instrument tray with non-porous single instrument
Flash 270°F (132°C)	270°F (132°C)	3	1	Unwrapped instrument tray with a single instrument
Flash 270°F (132°C)	270°F (132°C)	10	1	Unwrapped instrument tray with non-porous multiple instruments (max weight of 17lbs).

Table 1: Factory programmed Sterilization Cycles

Note on table 1: Factory set dry time is recommended minimum. Extended dry time may be required depending on local conditions.

The following table (Table 2) is Belimed Sauter AG's recommended load for the Series 8, Models 6-0-12 VS1 and 6-0-12 VS2.

Model Single door Double door	Sterilizer Chamber Size	Fabric packs, 11"x11"x 9", max. 6.6lbs each.	Wrapped Instrument Trays, 20"x 10", max. 17lbs each	Fabric packs, 23"x11"x11", max 17lbs each.
6-0-12 VS1 6-0-12 VS2	26" x 26" x 51.5" (660 x 660 x 1300)mm	16	12*	8

Table 2: Recommended Loads.

* The use of twelve (12) Instrument trays was validated using only rigid surgical and simulated instruments.

The following table (Table 3) is Belimed Sauter AG's guidelines for liquid cycle processing for Series 8, Models 6-0-12 VS1 and 6-0-12 VS2.

Model Single door Double door	Sterilizer Chamber Size	Volume of liquid in One Container	Number of Containers
6-0-12 VS1 6-0-12 VS2	26" x 26" x 51.5" (660 x 660 x 1300)mm	1000ml	88

Table 3, Guidelines for liquid 250°F cycle processing

The Belimed Steam Sterilizer TOP 5000 Series 8 is offered in the following size configurations:

26" x 26" x 51.5" (660mm x 660mm x 1300mm) Single door, Prevacuum
26" x 26" x 51.5" (660mm x 660mm x 1300mm) Double door, Prevacuum