510(k) Summary

K100622

Date: August,10, 2010

Submitter's Name / Address: Belimed Sauter AG
Zelgstrasse 8
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AUG 27 2010

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Trade Name: Belimed Steam Sterilizer MST-V

Model: 3-3-6

Classification: Steam Sterilizer – Class II, as listed per 21 CFR 880.6880
Product Code 80 FLE

Predicate Device: Belimed Steam Sterilizer TOP 5000
Model 5-5-9 (K060337)

DEVICE DESCRIPTION:

The Belimed Steam Sterilizers MST-V 3-3-6 is intended for use in hospital and health care facilities and is intended to be used in an identical manner as the Belimed Steam Sterilizer **Model 5-5-9.**
The small chamber size incorporates flexibility, and allows operating the sterilizers in rooms with limited space conditions.

NONCLINICAL COMPARISON TO THE PREDICATE DEVICE:

The Belimed Steam Sterilizer MST-V 3-3-6, is very similar to the predicate device.
Modifications made from the predicate device include:

- Smaller chamber size
- Optional Steam Generator Integrated
- Control system model and MMI (operating panel)

CLINICAL DATA:

No clinical data is required for this device classification submission.

INTENDED USE:

The Belimed Steam Sterilizer MST-V 3-3-6 is designed for sterilization of non-porous and porous heat and moisture-stable materials used in health care facilities..

The Belimed Steam Sterilizer MST-V 3-3-6 is equipped with the following factory-programmed sterilization cycles and cycle values (Table 1).

Table 1: Factory programmed sterilization cycles

No.	CYCLE	PRE-TREATMENT	STERILIZE TEMP. & *PRESSURE*	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	PreVac 270 long Dry	3 vacuum pulses: 90/100/100 mbar 2 Steam pulses: 1500/1500 mbar	270 °F 2880mbar	4 min	30 min	Two double wrapped instrument trays, maximum total weight of 50 lbs or 25lbs / tray
2	PreVac 270 short Dry	3 vacuum pulses: 90/100/100 mbar 2 Steam pulses: 1500/1500mbar	270 °F 2880mbar	4 min	5 min	Two Fabric Packs total weight of Maximum 9 lbs or One single wrapped instrument tray with non- porous single instrument
3	Prevac Flash 270	1 vacuum pulse: 90mbar	270 °F 2880mbar	4 min	1 min	One unwrapped instrument tray, maximum weight of 25 lbs or One unwrapped instrument tray with single instrument
4	Gravity 250	Purge time 4 min & Temp. > 98°C	250 °F 2050mbar	25 min	0 min	One unwrapped non-porous instrument tray, maximum weight of 25 lbs
5	Bowie-Dick Test	3 vacuum pulses: 90/100/100 mbar 2 Steam pulses: 1500/1500mbar	273 °F 3030mbar	3.5 min	1 min	Bowie-Dick- or other FDA cleared air removal test pack
6	Leak Test	Vacuum: 65mbar Test time: 15min	-	-	-	Empty chamber
7	Warm up & leak test	Vacuum: 65mbar Test time: 15min	270 °F 2880mbar	3 min	3 min	Empty chamber
8	PreVac 270 long Dry	3 vacuum pulses: 90/100/100 mbar 2 Steam pulses: 1500/1500mbar	270 °F 2880mbar	10 min	30 min	One double wrapped instrument tray, maximum total weight of 25 lbs
9	PreVac Flash 270	1 vacuum pulse: 90mbar	270 °F 2880mbar	10 min	1 min	One unwrapped instrument tray, maximum weight of 25 lbs or One single wrapped instrument tray with non- porous single instrument

Note on table 1: Factory set dry time is recommended minimum. Extended dry time may be required depending on local conditions.
Fabric load should be preconditioned between 68°F and 75°F and at a relative humidity of at least 35% to 60% for at least 2 hours.

The Belimed Steam Sterilizer MST-V 3-3-6 is offered in the following configurations:

Table 2: Dimensions

Model single door double door	Configuration	Chamber size (Volume) (L)	Chamber size (H x W x D) (inch)	(mm)	Overall Dimensions (H x W x D) (inch)	(mm)
3-3-6 VS1 3-3-6 VS2	1 door 2 door	73	13"x 13"x 25"	335 x 335 x 640	60"x 25"x 31"	1530 x 640 x 800

The Belimed Steam Sterilizer MST-V 3-3-6 is designed to be used for the terminal sterilization of porous and non-porous, heat and moisture stabile materials in the healthcare facilities.
Depending of the chosen cycle materials as different as textiles, unwrapped or wrapped instrument trays with single or multiple instruments may be sterilized.

The Belimed Steam Sterilizer MST-V 3-3-6 is factory equipped with cycles which have been tested in accordance with AAMI/ANSI ST8:2008 under defined load conditions. The predicate device with a chamber volume 73 l has been validated previously.

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 Advancement of Medical Instrumentation (AAMI). Prior to release, Belimed Steam Sterilizer MST-V 3-3-6 was validated to meet the requirements of AAMI/ANSI ST8:2008.

The results of the Belimed Steam Sterilizer MST-V 3-3-6 verification studies demonstrate that the sterilizer performs as intended and are summarized as follows:

- Empty chamber testing performed as described in Section 5.4.2.5 of ANSI/AMMI ST8:2008, for the PreVac, PreVac Flash and Gravity cycles. These cycles demonstrated the sterilizer's capability to provide steady state thermal conditions within the chamber that are corresponding with the predicted sterility assurance level (SAL) in the load. The sterilizer meets the requirements of Section 4.4.2.2 and 4.4.2.5 of ANSI/AAMI ST8.
- All PreVac cycles verified using the fabric test pack, as described in Section 5.5.2 AAMI/ANSI ST8:2008 were qualified according to section 5.5.2.5 ANSI/AAMI ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 of at least 12 minutes by half cycle, 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 5.5.4 of ANSI/AAMI ST8:2008. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 of at least 12 minutes by half cycle, 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 or single wrapped instrument trays were qualified according to section 5.5.5.2 AAMI/ANSI ST8:2008 and ANSI/AAMI ST79:2006 section 10.7. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 of at least 12 minutes by half cycle.
- All Gravity cycles verified using the unwrapped instrument tray, were qualified according to section 5.5.5.1 AAMI/ANSI ST8:2008. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time at temperature sufficient to produce an F_O of at least 12 minutes by half cycle.
- The Bowie Dick Test cycle was verified using the Bowie-Dick Test Pack was qualified according to section 5.6 of AAMI/ANSI ST8, and demonstrated a uniform color change throughout the test sheet and the load temperature devices attained the exposure temperature within 10 seconds of progressing into the exposure phase.
- 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 Premarket Submissions for Software Contained in Medical Devices (May 2005)"*.

SAFETY:

Belimed Sauter AG's sterilizers including the Belimed Steam Sterilizer MST-V 3-3-6 have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Belimed Steam Sterilizer MST-V complies with the following safety standards:

1. UL 61010-1:2005
2. IEC EN 61010-2-040:2005
3. IEC EN 60601-1-2:2001 +A1:2006
4. IEC EN 62304:2006
5. American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels Ed. 2007 +Add. 2008
6. EN ISO 14971:2007

Belimed has a certified quality management system according to ISO 9001 and ISO 13485.

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 MST-V 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.

USER INFORMATION

Belimed Sauter AG provides information to the user that is intended to insure safe and effective use of steam sterilization in its detailed User's Manual 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.

CONCLUSION

The Belimed Steam Sterilizer MST-V 3-3-6 is a substantially equivalent device to that of the predicate device. There have been no substantial changes in technology and intended use to the predicate device model 5-5-9 (K060337). This steam sterilizer MST-V 3-3-6 meets the applicable requirements of the applicable standards.
Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate device and is safe and effective when used as intended.

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

Belimed Sauter AG
C/O Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

AUG 2 7 2010

Re: K100622
Trade/Device Name: Belimed Steam Sterilizer MST-V 3-3-6
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: August 16, 2010
Received: August 23, 2010

Dear Mr. Preiss:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/ReportaProblem/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,

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

Enclosure

Indications for Use

K100622
AUG 27 2010

510(k) Number: K100622

Device Name: **Belimed Steam Sterilizer MST-V 3-3-6**

Indications for Use:

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Prescription Use _______ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use x OTC (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K100622