DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 12, 2017

Belimed AG
Jay Upchurch
Product Engineer, U.S. Agent
Belimed, Inc.
2325 Charleston Regional Parkway
Charleston, South Carolina 29412

Re: K170228
Trade/Device Name: Belimed Steam Sterilizer MST-H TOP 5000
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: April 6, 2017
Received: April 12, 2017

Dear Jay Upchurch:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170228

Device Name
Belimed Steam Sterilizer MST-H TOP 5000

Indications for Use *(Describe)*
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 MST-H TOP 5000 is equipped with the following factory programmed sterilization cycles and cycle values. This is shown in Table 1.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Table 1: Factory programmed sterilization cycles and cycle values.

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
PREVAC 270F (132ºC)	270°F (132ºC)	4 minutes	30 minutes	Double-wrapped instrument trays. Maximum weight of 25 lbs. each for the following models: 9-6-12 HS2, 9-6-15 HS1, and GR 9-6-18 HS2. Maximum weight of 17 lbs. each for the following models: 9-6-9 HS1, 9-6-9 HS2, 9-6-12 HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1. Fabric Packs.
PreVac 270F 4S / 5Dry (132ºC)	270°F (132ºC)	4 minutes	5 minutes	Fabric Packs.
Liquid 250F (121ºC)	250°F (121ºC)	45 minutes	0 minute	Max 1000 ml of Liquid per bottle. Use only vented bottles, type I, borosilicate glass.
Express 270F (132ºC)	270°F (132ºC)	4 minutes	3 minutes	Single wrapped instrument tray with non-porous single instrument.
Immediate Use 270F - Single Ins (132ºC)	270°F (132ºC)	3 minutes	1 minute	Unwrapped instrument tray with a single instrument.
Immediate Use 270F - Multi Ins (132ºC)	270°F (132ºC)	10 minutes	1 minute	Unwrapped instrument tray with non-porous multiple instruments. Maximum weight of 25 lbs each for the following models: 9-6-12 HS2, 9-6-15 HS1, and GR 9-6-18 HS2. Maximum weight of 17 lbs. each for the following models: 9-6-9 HS1, 9-6-9 HS2, 9-6-12HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1. Maximum of 4 instrument trays.

510(k) Summary

K170228

Date:	May 5, 2017
Owner's Name / Address:	Belimed AG Grienbachstrasse 11 CH-6300 Zug / Switzerland
Preparer's Name / Address:	Belimed, Inc. 2325 Charleston Regional Parkway Charleston, SC 29412 USA
Contact Person:	Jay Upchurch Email: Jay.Upchurch@Belimed.com Phone: (843) 216-7424 x133 Fax: (843) 216-7707
Trade Name:	Belimed Steam Sterilizer MST-H TOP 5000
Models:	9-6-9 HS1, 9-6-9 HS2, 9-6-12 HS1, 9-6-12 HS2, 9-6-15 HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1, and GR 9-6-18 HS2.
Classification:	Steam Sterilizer - Class II, as listed per 21 CFR 880.6880 Product Code: FLE
Predicate Device:	Belimed Steam Sterilizer TOP 5000 Series 9-18 (K021223)

INTENDED 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 MST-H TOP 5000 is equipped with the following factory programmed sterilization cycles and cycle values. This is shown in Table 1.

Table 1: Factory programmed sterilization cycles and cycle values.

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
PREVAC 270F (132ºC)	270°F (132ºC)	4 minutes	30 minutes	Double-wrapped instrument trays. Maximum weight of 25 lbs. each for the following models: 9-6-12 HS2, 9-6-15 HS1, and GR 9-6-18 HS2. Maximum weight of 17 lbs. each for the following models: 9-6-9 HS1, 9-6-9 HS2, 9-6-12 HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1. Fabric Packs.
PreVac 270F 4S / 5Dry (132ºC)	270°F (132ºC)	4 minutes	5 minutes	Fabric Packs.
Liquid 250F (121ºC)	250°F (121ºC)	45 minutes	0 minute	Max 1000 ml of Liquid per bottle. Use only vented bottles, type I, borosilicate glass.
Express 270F (132ºC)	270°F (132ºC)	4 minutes	3 minutes	Single wrapped instrument tray with non-porous single instrument.
Immediate Use 270F - Single Ins (132ºC)	270°F (132ºC)	3 minutes	1 minute	Unwrapped instrument tray with a single instrument.
Immediate Use 270F - Multi Ins (132ºC)	270°F (132ºC)	10 minutes	1 minute	Unwrapped instrument tray with non-porous multiple instruments. Maximum weight of 25 lbs each for the following models: 9-6-12 HS2, 9-6-15 HS1, and GR 9-6-18 HS2. Maximum weight of 17 lbs. each for the following models: 9-6-9 HS1, 9-6-9 HS2, 9-6-12HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1. Maximum of 4 instrument trays.

DESCRIPTION OF DEVICE:

The Belimed Steam Sterilizers MST-H, models 9-6-9, 9-6-12, 9-6-15, and 9-6-18 are available in a single door (HS1) or double door (HS2) version.
The sterilizers are available in a carriage loader and a ground loader (GR) version.

The sterilizers are equipped with Prevacuum, Gravity, Liquid, Air Leak Test and Bowie-Dick Test cycles.

The Belimed Steam Sterilizers TOP 5000 are equipped with the following predefined cycles (Table 2):

Table 2: Factory programmed sterilization and test cycles.

No.	CYCLE	PRE-TREATMENT	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	PreVac 270F 4S / 30Dry	4 pulses	270°F	4 minutes	30 minutes	Double-wrapped instrument trays. Maximum weight of 25 lbs each for the following models: 9-6-12 HS2, 9-6-15 HS1, and GR 9-6-18 HS2. Maximum weight of 17 lbs. each for the following models: 9-6-9 HS1, 9-6-9 HS2, 9-6-12 HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1. Fabric Packs.
2	PreVac 270F 4S / 5Dry	4 pulses	270°F	4 minutes	5 minutes	Fabric Packs.
3	Immediate Use 270F - Single Ins	Purge	270°F	3 minutes	1 minute	Unwrapped instrument tray with a single instrument
4	Immediate Use 270F - Multi Ins	Purge	270°F	10 minutes	1 minute	Unwrapped instrument tray with non porous multiple instruments. Maximum weight of 25 lbs each for the following models: 9-6-12 HS2, 9-6-15 HS1, and GR 9-6-18 HS2. Maximum weight of 17 lbs. each for the following models: 9-6-9 HS1, 9-6-9 HS2, 9-6-12HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1. Maximum of 4 instrument trays.
5	Express 270F	2 pulses	270°F	4 minutes	3 minutes	Single wrapped instrument tray with non porous single instrument
6	Bowie-Dick Test	4 pulses	273°F	3.5 minutes	1 minute	One DART or Bowie-Dick-Test-Pack
7	Leak Test	Vacuum: 65 mbar Test time: 15 min	-	-	-	Empty chamber
8	Warm up & Leak Test	Vacuum: 65 mbar Test time: 15 min	270°F	4 minutes	3 minutes	Empty chamber
9	-		-	-	-	-

10	Liquid 250F	Purge	250°F	45 minutes	-	Max 1000 ml of Liquid per bottle. Use only vented bottles, type I, borosilicate glass Cycle disabled

Notes on Table 2:
1. Factory set sterilize time is recommended.
2. Factory set dry time.
3. Recommended load: Refer to table 4 and 5.
4. 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.
5. The liquid cycle is for non-patient contact use only.

The Belimed Steam Sterilizers MST-H are offered in the following versions:

Table 3. Versions and dimensions.

Model Single Door Double Door	Configuration	Chamber Size (H x W x D) (mm)	Overall Size (H x W x D) (mm)
9-6-9 HS1 GR 9-6-9 HS1	1 door	1080 x 660 x 1040 1230 x 660 x 1100	2000 x 1700 x 1280 2000 x 1900 x 1600
9-6-9 HS2 GR 9-6-9 HS2	2 door	1080 x 660 x 1040 1230 x 660 x 1100	2000 x 1700 x 1300 2000 x 1900 x 1600
9-6-12 HS1 GR 9-6-12 HS1	1 door	1080 x 660 x 1398 1230 x 660 x 1400	1970 x 1700 x 1714 2000 x 1900 x 1900
9-6-12 HS2 GR 9-6-12 HS2	2 door	1080 x 660 x 1398 1230 x 660 x 1400	1970 x 1700 x 1714 2000 x 1900 x 1900
9-6-15 HS1 GR 9-6-15 HS1	1 door	1080 x 660 x 1700 1230 x 660 x 1706	1970 x 1700 x 2022 2000 x 1900 x 2200
9-6-15 HS2 GR 9-6-15 HS2	2 door	1080 x 660 x 1700 1230 x 660 x 1706	1970 x 1700 x 2022 2000 x 1900 x 2200
9-6-18 HS1 GR 9-6-18 HS1	1 door	1080 x 660 x 2014 1230 x 660 x 2000	1970 x 1700 x 2330 2000 x 1900 x 2500
9-6-18 HS2 GR 9-6-18 HS2	2 door	1080 x 660 x 2014 1230 x 660 x 2000	1970 x 1700 x 2330 2000 x 1900 x 2500

The following tables show the recommended loads for the Belimed Steam Sterilizers MST-H:

Table 4: Recommended loads by sterilizer for 17 lb. instrument trays and fabric packs.

Sterilizer Chamber Size (mm)	Model	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)	9-6-9 HS1 and 9-6-9 HS2	9	18	9
26”x 42.5”x 55” (660 x 1080 x 1400)	9-6-12 HS1	12	30	12
26”x 42.5”x 67” (660 x 1080 x 1700)	9-6-15 HS2	15	36	15
26”x 42.5”x 79” (660 x 1080 x 2000)	9-6-18 HS1 and 9-6-18 HS2	18	42	18
26”x 48.5”x 43” (660 x 1230 x 1100)	GR 9-6-9 HS1 and GR 9-6-9 HS2	9	18	9
26”x 48.5”x 55” (660 x 1230 x 1400)	GR 9-6-12 HS1 and GR 9-6-12 HS2	12	30	12
26”x 48.5”x 67” (660 x 1230 x 1700)	GR 9-6-15 HS1 and GR 9-6-15 HS2	15	36	15
26”x 48.5”x 79” (660 x 1230 x 2000)	GR 9-6-18 HS1	18	42	18

Table 5: Recommended loads by sterilizer for 25 lb. instrument trays and fabric packs.

Sterilizer Chamber Size (mm)	Model	Wrapped Instrument Trays 20”x10” max. 25 lb. each	Fabric Packs 11”x11”x9” max 6.6lb each	Fabric Packs 23”x11”x11” max. 17lb each
26”x 42.5”x 55” (660 x 1080 x 1400)	9-6-12 HS2	12	30	12
26”x 42.5”x 67” (660 x 1080 x 1700)	9-6-15 HS1	15	36	15
26”x 48.5”x 79” (660 x 1230 x 2000)	GR 9-6-18 HS2	18	42	18

Table 6. Recommended loads for liquid cycle 250F.

Model	Volume of Liquid in One Container	Number of Containers
9-6-9 GR 9-6-9	1000 mL	126
9-6-12 GR 9-6-12	1000 mL	168
9-6-15 GR 9-6-15	1000 mL	210
9-6-18 GR 9-6-18	1000 mL	252

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

The Belimed Steam Sterilizers MST-H, models 9-6-9 HS1, 9-6-9 HS2, 9-6-12 HS1, 9-6-12 HS2, 9-6-15 HS1, 9-6-15 HS2, 9-6-18 HS1, 9-6-18 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, GR 9-6-12 HS1, GR 9-6-12 HS2, GR 9-6-15 HS1, GR 9-6-15 HS2, GR 9-6-18 HS1, and GR 9-6-18 HS2 are designed for the sterilization of non-porous and porous heat and moisture stable materials used in healthcare facilities.

NONCLINICAL COMPARISON TO THE PREDICATE DEVICE:

The Belimed Steam Sterilizers MST-H, models 9-6-9, 9-6-12, 9-6-15, and 9-6-18 are very similar to the predicate device.
A summary of the differences to the predicate device is included in Table 7.

Table 7. A summary of the differences to the predicate device.

General Sterilizer Features	Belimed Steam Sterilizer TOP 5000 Series 9-18 (K021223)	Belimed Steam Sterilizer TOP 5000 Series 9-18	Comparison
Intended Use	Terminal Sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities	Terminal Sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities	Same
Operating principle	The sterilizing agent is steam.	The sterilizing agent is steam.	Same
Built according to standard	ANSI/AAMI ST8:1994 Hospital Steam Sterilizers	ANSI/AAMI ST8:2013 Hospital Steam Sterilizers	Same
Chamber sizes Model: 9-6-9 / 9-6-12 / GR9-6-12 9-6-15 / GR9-6-15 9-6-18 / GR9-6-18	(H x W x D) in mm: 1080x660x1040 1080x660x1400 / 1230x660x1400 1080x660x1700 / 1230x660x1700 1080x660x2000 / 1230x660x2000	(H x W x D) in mm: 1080x660x1040 1080x660x1400 / 1230x660x1400 1080x660x1700 / 1230x660x1700 1080x660x2000 / 1230x660x2000	Same
Sterilization cycles	PreVac 270 °F Gravity 270 °F Liquid 250 °F Bowie Dick Test Air Leak Test	PreVac 270 °F Gravity 270 °F Liquid 250 °F Bowie Dick Test Air Leak Test	Same
Max. instrument tray weight	17 lbs.	17 lbs. for 9-6-9 HS1 9-6-9 HS2, GR 9-6-9 HS1, GR 9-6-9 HS2, 9-6-12 HS1, GR 9-6-12HS1, 9-6-15 HS2, GR 9-6-15 HS1, GR 9-6-15 HS2, 9-6-18 HS1, 9-	Same

		6-18 HS2, GR 9-6-18 HS1 25 lbs. for 9-6-12 HS2, 9-6-15 HS1, and GR 9-6-18 HS2	
Load capacity instrument trays Model: 9-6-9 / 9-6-12 / GR9-6-12 9-6-15 / GR9-6-15 9-6-18 / GR9-6-18	 9 12 15 18	 9 12 15 18	Same
Chamber material	Stainless steel 316L	Stainless steel 316L	Same
Chamber design pressure	39 psi	39 psi	Same
Door construction	Automated horizontal sliding door(s)	Automated horizontal sliding door(s)	Same
Safety (pressure relief) valves	ASME approved	ASME approved	Same
Piping	Stainless steel 316 L	Stainless steel 316 L	Same
Electrical	3 phase 208V 60Hz	3 phase 208V 60Hz	Same
HMI Technology	LCD color / 5.7”	LCD color / 5.7”	Same
Control Technology	PLC	PLC	Same
Printer Technology	Matrix Dot Technology	Matrix Dot Technology	Same
Vacuum pump	9-6-9 / GR 9-6-9: 95m3/h 9-6-12 / GR 9-6-12: 95m3/h 9-6-15 / GR 9-6-15: 130m3/h 9-6-18 / GR 9-6-18: 130m3/h	9-6-9 / GR 9-6-9: 95m3/h 9-6-12 / GR 9-6-12: 95m3/h 9-6-15 / GR 9-6-15: 130m3/h 9-6-18 / GR 9-6-18: 130m3/h	Same
Air filter	0.3 microns	0.3 microns	Same

CLINICAL DATA:

No clinical data is required for this device classification submission.

SUMMARY OF PERFORMANCE TESTING:

Belimed 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-H were validated to meet the requirements of ANSI/AAMI ST8:2013.

The results of the Belimed Steam Sterilizer MST-H verification studies demonstrate that the sterilizer performs as intended and is summarized as follows:

- The Prevac cycle where the maximum tray capacity is changing to 25 lbs. was qualified according to AAMI ST8:2013 section 5.5.4. This cycle 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 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.
- The Immediate Use Gravity cycle where the maximum tray capacity is changing from 17 lbs. to 25 lbs. was qualified according to AAMI ST8:2013 section 5.5.5.1.

STANDARDS USED:

Belimed's sterilizers, including the Belimed Steam Sterilizer MST-H, models 9-6-12, 9-6-15, and 9-6-18, have been designed and constructed to meet the safety and performance requirements of various national safety codes and standards. The Belimed Steam Sterilizer MST-H complies with the following safety standards:

1. ANSI/AAMI ST8:2013
2. ANSI/AAMI ST79:2010+A1:2010
3. IEC EN 62304:2006
4. EN ISO 14971:2012
5. ISO 13485:2012 Medical Devices – Quality management systems. Requirements for regulatory purposes
6. IEC EN 60601-1-2:2007
7. American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels Ed. 2015.
8. UL 61010-1:2004 Safety requirements for electrical equipment for measurement, control and laboratory use -Part 1: General requirements.
9. IEC 61010-2-040:2005 Safety requirements for electrical equipment for measurement, control and laboratory use -Part 2: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.

CONCLUSION

The Belimed Steam Sterilizer MST-H Top 5000 is substantially equivalent device to that of the predicate device (K021223).

The nonclinical tests and accompanying information in this premarket notification demonstrate that this device is as safe, as effective, and performs as well or better than the predicate device series (K021223).