510(k) SUMMARY

K103504

MAR 16 2011

Getinge Model 400HC/500HC Series Steam Sterilizer

Submitted by: Getinge Sourcing LLC
1777 E Henrietta Road
Rochester, NY 14623-3133

Contact Person: Barb Smith
Sr. Manager, Regulatory Affairs
Phone: (585) 214-6049
Fax: (585) 272-5299

Date prepared: October 26, 2010

Proprietary Name: Model 400HC/500HC Series Steam Sterilizer

Common Name: Steam Sterilizer

Device Classification: Steam Sterilizer (80 FLE)

Class II, as listed per 21 CFR 880.6880

Predicate Device: Model 400HC/500HC Series Steam Sterilizer [K012573]

Description of Device:

The Getinge Models 422HC, 433HC, 522HC and 533HC steam sterilizers are the same model designations as the predicate device (K012573). Modifications to the device have been made to include control software updates, vessel material change and the options for a vacuum pump system (in place of water ejector) and stainless steel piping and components (in place of brass piping and components). The modifications made to the 400HC/500HC series Steam Sterilizer do not affect the intended use of the device and do not alter the fundamental science technology of the device. The modifications were made under the procedures and processes of the documented design control process. Performance testing of the modified device models was to ANSI/AAMI ST8:2008.

K103504

List of available cycles
Model 433HC and 533HC Steam Sterilizer Cycles and Load Chart

Cycle Type	No. of Available Cycles	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Size	
		Exp. Temp.	Exp. Time	Dry Time		433HC	533HC
PREVAC 1 (vac)	3	275°F (135°C)	3 min	16 min	Double-wrapped instrument trays, up to 25 lb per tray	2	3
					Fabric packs	4	12
PREVAC 2 (vac)	2	275°F (135°C)	3 min	3 min (Note 4)	Single wrapped, single instrument	1	1
					Single wrapped instrument trays, up to 25 lb per tray	2	3
					Fabric packs	4	12
PREVAC 3 (vac)	1	275°F (135°C)	3 min	0 min (Note 4)	Unwrapped porous or non-porous single instrument	1	1
					Unwrapped porous & non-porous instrument trays, up to 25 lbs. per tray.	2	2
B & D Test (vac)	1	273°F (134°C)	3 min, 30 sec	0 min	S.M.A.R.T. Pack or equivalent (1) in an EMPTY chamber	1 Test Pack	1 Test Pack
GRAVITY 1 (grv)	3	250°F (121°C)	30 min	45 min	Double-wrapped instrument trays, up to 25 lb per tray	2	3
					Fabric packs	4	12
GRAVITY 2 (grv)	3	275°F (135°C)	10 min	45 min	Double-wrapped instrument trays, up to 25lb per tray	2	3
					Fabric packs	4	12
Flash 3+ (f 3) (Notes 1,7)	4	275°F (135°C)	3 min	30 sec (Note 4)	Unwrapped non-porous single instrument	1	1
					Unwrapped non-porous instrument trays, up to 25 lb per tray	2	2
Flash 10+ (f10) (Notes 1,7)	2	275°F (135°C)	10 min	30 sec (Note 4)	Unwrapped porous or non-porous single instrument	1	1
					Unwrapped porous & non-porous instrument trays, up to 25 lb per tray	2	2
LIQUIDS 1 (liq)	1	250°F (121°C)	30 min	0.75 psi/min (Note 3)	Each container 1000 mL or smaller	15	32
LIQUIDS 2 (liq)	1	250°F (121°C)	45 min	0.75 psi/min (Note 3)	Each container 1000 mL or smaller	15	32

K103504

Leak Test (lk) (Note 2)	1	268°F (131°C)	3 min	15 min dry, 5 min equalize, 15 min test	Empty chamber	--	--

NOTE: Liquid Cycles are not intended for the sterilization of liquids used for direct patient contact.

Model 422HC and 522HC Steam Sterilizer Cycles an Load Chart

Cycle Type	No. of Available Cycles	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Size	
		Exp. Temp.	Exp. Time	Dry Time		422HC	522HC
GRAVITY 1 (grv)	3	250°F (121°C)	30 min	45 min	Double-wrapped instrument trays, up to 25 lb per tray	2	3
					Fabric packs	4	12
GRAVITY 2 (grv)	3	275°F (135°C)	10 min	45 min	Double-wrapped instrument trays, up to 25 lb per tray	2	3
					Fabric packs	4	12
Flash 3+ (f 3) (Notes 1, 7)	4	275°F (135°C)	3 min	30 sec (Note 4)	Unwrapped non-porous single instrument	1	1
					Unwrapped non-porous instrument trays, up to 25 lb per tray	2	2
Flash 10+ (f10) (Notes 1, 7)	2	275°F (135°C)	10 min	30 sec (Note 4)	Unwrapped porous or non-porous single instrument	1	1
					Unwrapped porous & non-porous instrument trays, up to 25 lb per tray	2	2
LIQUIDS 1 (liq)	1	250°F (121°C)	30 min	0.75 psi/min (Note 3)	Each container 1000 mL or smaller (Notes 5,6,8)	15	32
LIQUIDS 2 (liq)	1	250°F (121°C)	45 min	0.75 psi/min (Note 3)	Each container 1000 mL or smaller (Notes 5, 6, 8)	15	32

NOTE: Liquid Cycles are not intended for the sterilization of liquids used for direct patient contact.

TABLE NOTES

1. Load configurations during testing validations follow *AAMI Standard ST8 Hospital Steam Sterilizers* where applicable. All Fabric Packs and instrument trays formulated as described in *AAMI Standard ST8 Hospital Steam Sterilizers.*

   For guidance on loading the sterilizer, refer to *AAMI Standard ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
2. Vacuum leak test parameters are not adjustable.
3. Cooldown rate
4. At the end of a flash cycle, PREVAC 2 cycle, or a PREVAC 3 cycle, items may NOT be dry. Drying time may be added if required.
5. User facility must validate the cycle if the load includes containers larger than 1000 mL.
6. Use vented or open containers only.
7. The recommended minimum exposure time and temperature for unwrapped, nonporous, flash cycle loads (e.g. metal instruments) is 3 minutes at 275°F (135°C).
8. A small load of one-liter containers requires an exposure time of 45 min.

K103504

Intended Use:

The Getinge 400HC/500HC Series Steam Sterilizer is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.

Predicate Device

Getinge 400HC/500HC Series Steam Sterilizers [K012573].

Comparisons to Predicate Device:

The modified 400HC/500HC Series Steam Sterilizer has the same model designation as the predicate device. Modifications were made to the predicate device are summarized below:

1) The operating system has been upgraded to allow more inputs and outputs but the same fundamental micro processor technology is used.

2) Vessel material has changed from Stainless Steel SA240 UNS S31803/Type 2205 to Stainless Steel SA240-316Ti. Both materials meet ASME Boiler Pressure Vessel Code Section II - Part A – Materials – Ferrous Material Specifications.

3) The modified device offers the option for a vacuum pump system in place of a water ejector. The benefit of this option is to reduce utility water consumption.

4) The modified device offers the option of stainless steel process piping and components. With this option all piping in contact with media that could contact chamber load are ANSI 304 or ANSI 316 stainless steel.

5) The modified 400HC/500HC Series Sterilizer was tested to the requirements in ANSI/AAMI ST8:2008.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The 400HC/500HC Series Steam Sterilizer is a substantially equivalent device to that of the predicate device. There have been no substantial changes in technology and no changes to the intended use of this device. This steam sterilizer meets the applicable requirements of AAMI ST8:2008 performance 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Barb Smith
Senior Manager, Regulatory Affairs
Getinge Sourcing, LLC
1777 E Henrietta Road
Rochester, New York 14623-3133

MAR 16 2011

Re: K103504
Trade/Device Name: 400HC/500HC Series Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: February 24, 2011
Received: February 25, 2011

Dear Ms. Smith:

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,

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

510(k) Number (if known): K103504

Device Name: 400HC/500HC Series Steam Sterilizer

Indications for Use: The Getinge 400HC/500HC Series Steam Sterilizer is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie - Wells

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

510(k) Number: K103504