K122071

510(k) SUMMARY

MAR 12 2013

Getinge 400HC-E/500HC-E Series Steam Sterilizer

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

Contact Person: Barb Smith, RAC
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Date prepared: July 10, 2012

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

Common Name: Steam Sterilizer

Device Classification: Steam Sterilizer (80 FLE)

Class II, as listed per 21 CFR 880.6880

Predicate Device: Getinge Model 700HC-E Series Steam Sterilizer [K120441]

Getinge Model 400HC/500HC Series Steam Sterilizer [K103504]

Description of Device:

The Getinge 400HC-E/500HC-E Series Steam Sterilizer is designed for sterilization of heat and moisture stable materials used in healthcare facilities. The model designations provided in the 400HC-E/500HC-E Series Steam Sterilizer are 422HC-E, 433HC-E, 522HC-E and 533HC-E.

The 400HC-E/500HC-E Steam Sterilizer employs both gravity/downward displacement with positive pulse conditioning and pressure/vacuum pulsing for dynamic air removal. Up to 24 cycles can be easily accessed and custom cycle names can be designated by the user (duplicate cycles are provided to allow for user designated names). All cycle phases are sequenced and monitored by the control system, providing both audible and visual notification of deviation from certain operating parameters.

List of available cycles:
Model 433HC-E and 533HC-E 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-E	533HC-E
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
PREVAC 4 (vac)	1	270°F (132°C)	4 min	16 min	Double-wrapped instrument trays, up to 25 lb per tray	2	3
					Fabric Packs	4	12
PREVAC 5 (vac)	1	270°F (132°C)	4 min	3 min (Note 4)	Fabric Packs	4	12
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
IMMED USE 3+ (ius) (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

IMMED USE 10+ (ius) (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
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-E and 522HC-E 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-E	522HC-E
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
IMMED USE 3+ (ius) (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
IMMED USE 10+ (ius) (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. The load configurations listed in these tables are those used during testing validations of the sterilizer. These configurations follow *AAMI Standard ST8: Hospital steam sterilizers* where

applicable (fabric packs are process challenge devices as described in ANSI/AAMI ST8 and were made to be consistent with the packs described in ANSI/AAMI ST8).

For guidance on processing loads in 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 an immediate use cycle, PREVAC 2 cycle, PREVAC 3 cycle, or a PREVAC 5 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) or 4 minutes at 270°C (132°C).
8. A small load of one-liter containers requires an exposure time of 45 min.

Intended Use:

The Getinge 400HC-E/500HC-E 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.

Comparisons to Predicate Device:

Similarities between the Getinge 400HC-E/500HC-E Series Steam Sterilizer and the identified predicates are:

- Intended use is the same: Intended for use by health care facilities to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.
- Operating Principle is the same: Saturated steam is the sterilizing agent.
- Materials of construction are the same: Vessel material is Stainless Steel SA240-316Ti. There is no direct patient contact associated with this device.
- Cycle Types: The cycle types offered are the same; Prevac (135°C, 132°C), Gravity (121°C, 135°C), Immediate Use (135°C) and Liquids 121°C (not for sterilization of liquids used directly for patient contact).
- Performance Testing: Factory recommended cycles were tested per industry standards and guidelines and effectiveness of sterilizer function was demonstrated by complete kill of biological indicators. Getinge Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8:2008 Hospital Steam Sterilizers.

The differences between the Getinge 400HC-E/500HC-E Series Steam Sterilizer and the predicate devices are:

- The Getinge 400HC-E/500HC-E Series Steam Sterilizer provides the addition of 132°C Prevac cycles and a touch screen user interface as cleared on the 700HC-E Series Steam Sterilizer as K120441.

Summary of Performance Testing:

Factory recommended cycles were tested per industry standards and guidelines and effectiveness of sterilizer function was demonstrated by complete kill of biological indicators. Getinge Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8:2008 Hospital Steam Sterilizers.
The results of Getinge 400HC-E/500HC-E Series Steam Sterilizer validation testing demonstrate that the sterilizer performs as intended. Summary of testing:

- Empty chamber testing performed for all cycles as described in ANSI/AAMI ST8:2008 Hospital Steam Sterilizers section 5.4.2.5. The results demonstrated that the sterilizer is capable of providing steady-state thermal conditions within the chamber that are consistent with the predicated sterility assurance level (SAL) in the load.

- All PREVAC and GRAVITY cycles were validated using fabric process challenge packs as described in ANSI/AAMI ST8:2008 section 5.5.2. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and moisture retention of less than 3% increase in pre-sterilization test pack weight including no visible wet spots.

- All PREVAC (excluding PREVAC 2 and PREVAC 5 that have shortened drying times) and GRAVITY cycles were validated using wrapped instrument process challenge devices as described in ANSI/AAMI ST8:2008 section 5.5.4. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and moisture retention of less than 20% increase in pre-sterilization weight of the towel including no visible wet spots on the outer wrapper.

- All Immediate Use (Flash) cycles were validated using a unwrapped non-porous process challenge device as described in ANSI/AAMI ST8:2008 section 5.5.5. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12 and complete BI kill.

- Liquid loads cycles were validated using 3 one liter flasks as described in ANSI/AAMI ST8:2008 section 5.5.3. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and water loss not exceeding 50ml.

- Bowie Dick cycle was validated using the Bowie-Dick test pack as described in ANSI/AAMI ST8:2008 section 5.6.1.1.

- The software validation for the cycle operation was performed according to FDA guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (5/11/2005)*".

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The 400HC-E/500HC-E Series Steam Sterilizer has the same intended use and technological characteristics as the predicate devices. The 400HC-E/500HC-E Series Steam Sterilizer meets the applicable requirements of AAMI ST8:2008 performance standards. Based on the information provided in this premarket notification, it can be concluded that the subject device is substantially 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 Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2013

Ms. Barb Smith, RAC
Senior, Manager Regulatory
Getinge Sourcing, LLC
1777 East Henrietta Road
ROCHESTER NY 14623-3133

Re: K122071
Trade/Device Name: 400HC-E/500HC-E Series Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: February 6, 2013
Received: February 7, 2013

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.

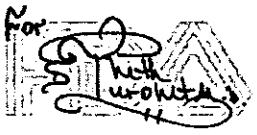
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122071

Device Name: 400HC-E/500HC-E Series Steam Sterilizer

Indications for Use: The Getinge 400HC-E/500HC-E Series Steam Sterilizer is intended for use by health care facilities 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
2013.03.07 17:34:59 -05'00'

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

510(k) Number: K122071

List of available cycles
Model 433HC-E and 533HC-E 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-E	533HC-E
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
PREVAC 4 (vac)	1	270°F (132°C)	4 min	16 min	Double-wrapped instrument trays, up to 25 lb per tray	2	3
					Fabric Packs	4	12
PREVAC 5 (vac)	1	270°F (132°C)	4 min	3 min (Note 4)	Fabric Packs	4	12
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
IMMED USE 3+ (ius) (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

IMMED USE 10+ (ius) (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
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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-E and 522HC-E 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-E	522HC-E
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
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IMMED USE 3+ (ius) (Notes 1, 7)	4	275°F (135°C)	3 min	30 sec (Note 4)	Unwrapped non-porous single instrument	1	1
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IMMED USE 10+ (ius) (Notes 1, 7)	2	275°F (135°C)	10 min	30 sec (Note 4)	Unwrapped porous or non-porous single instrument	1	1
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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
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NOTE: Liquid Cycles are not intended for the sterilization of liquids used for direct patient contact.

TABLE NOTES

1. The load configurations listed in these tables are those used during testing validations of the sterilizer. These configurations follow *AAMI Standard ST8: Hospital steam sterilizers* where applicable (fabric packs are process challenge devices as described in ANSI/AAMI ST8 and were made to be consistent with the packs described in ANSI/AAMI ST8).

   For guidance on processing loads in 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 an immediate use cycle, PREVAC 2 cycle, PREVAC 3 cycle, or a PREVAC 5 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.

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

510(k) Number: K122071