APR 5 - 2007

K070657

510(k) SUMMARY

Model 633HC Series Vacuum/Gravity Steam Sterilizer
(Sterilizer Models with 26", 39" and 51" lengths)

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

Contact Person: Ann G. Wheeler
Sr. Quality Assurance Engineer
Phone: (585) 272-5036
Fax: (585) 272-5299

Date prepared: April 5, 2007

Proprietary Name: Model 633HC Series Vacuum/Gravity Steam Sterilizer (Sterilizer Model with lengths 26", 39" and 51")

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 633HC Series Vacuum/Gravity Steam Sterilizer is intended for use in hospital and health care facilities. The device is an intermediate sized sterilizer within our product offering, it has a vertical sliding power door, upgraded control system and offers similar overall features as those on the Getinge 400HC/500HC Steam Sterilizers including a control panel (user interface) that incorporates a color display with soft key menu navigation, has the same cycle types with similar number of preset cycle types offered.

List of available cycles

Model 633HC Series Vacuum/GravitySteam Sterilizer Load Chart

Cycle Type	No. of Available Cycles	Factory Settings			Load Configuration[2]	Maximum Items per Chamber Sterilzer Model Length		
		Exp. Temp.	Exp. Time	Dry Time[1]		26"	39"	51"
PREVAC 1 (vac)	6	275°F (135°C)	3 min.	16 min.	• Double-wrapped instrument trays, up to 16 lbs (per tray).	4	8	12
					• Fabric packs	8	18	24
PREVAC 2 (vac)	2	275°F (135°C)	3 min.	3 min.	• Fabric packs	8	18	24
Bowie-Dick Test (vac)	1	273°F (134°C)	3 min. 30 sec.	0 min.	S.M.A.R.T. Pack or equivalent (1 max.) In an EMPTY cham ber	1 Test Pack	1 Test Pack	1 Test Pack
GRAVITY 1 (grv)	3	250°F (121°C)	30 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs (per tray).	4	8	12
					• Fabric packs	8	18	24
GRAVITY 2 (grv)	3	275°F (135°C)	10 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs (per tray).	4	8	12
					• Fabric packs	8	18	24
Flash 3+ (f 3)	2	275°F (135°C)	3 min.	30 sec.[5]	• Unwrapped non-porous single instrument	1	1	1
					• Unwrapped non-porous instrument trays, up to 16 lbs (per tray).	2	2	2
Flash 10+ (f10)	2	275°F (135°C)	10 min.	30 sec.[5]	• Unwrapped porous or non-porous single instrument	1	1	1
					• Unwrapped porous & non-porous instrument trays, up to 16 lbs (per tray).	2	2	2
LIQUIDS (liq)	1	250°F (121°C)	45 min.	0.75 psi/min.[4]	Up to 1000 mL containers	60	80	100
Vacuum Leak Test (lkt)[3]	1	268°F (131°C)	3 min.	15 min. dry 5 min. dwell 15 min. test	Empty chamber	-----	-----	-----

Notes for Table

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Load configurations follow AAMI Standards *ST8 Hospital Steam Sterilizers* where applicable.

[1]Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions. Gravity cycle drying time may be reduced by selecting vacuum drying phase.

[2]Refer to AAMI Standards ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

[3]Vacuum leak test cycle parameters are not adjustable.

[4]Cooldown rate

[5]Items may NOT be dry. Dry time may be added if required.

Intended Use:

The Model 633HC Series Vacuum/Gravity Steam Sterilizer is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments, linens and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

Predicate Device

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

Nonclinical Comparisons to Predicate Device

In summary, the differences between the 633HC Series and the predicate 400HC/500HC Series are:

1) The 633HC door drive mechanism is designed to accommodate a slightly larger and heavier door. The predicate 400HC/500HC Series power door utilizes a counter weight and pulley that engages with a small motor to drive the doors vertical movement. The 633HC uses a motorized lead screw to accomplish the same vertical door movement.

2) The frame material for the predicate is carbon steel welded construction, the 633HC is an aluminum extrusion framing that is secured with together with joining plates and hardware.

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

4) Vessel material has changed both materials meet ASME BPVC Section II - Part A – Materials – Ferrous Material Specifications.

5) The 633HC series has a larger vessel size range than the 400HC/500HC. It is an intermediate size within he steam sterilizer offered by Getinge Sourcing LLC.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The 633HC Series Vacuum/Gravity 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 ST8:2001 and CSA-Z314.7 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
9200 Corporate Boulevard
Rockville MD 20850

APR 5 - 2007

Ms. Ann G. Wheeler
Senior Quality Assurance Engineer
Getinge Sourcing, LLC
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K070657
Trade/Device Name: 633HC Series Vacuum/Gravity Steam Sterilizers
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: March 8, 2007
Received: March 9, 2007

Dear Ms. Wheeler:

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.

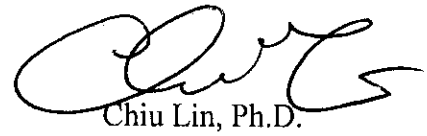
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): K070657

Device Name: 633HC Series Vacuum/Gravity Steam Sterilizer (Sterilizer Model with lengths 26", 39" and 51")

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Table 1: Model 633HC Series Vacuum/GravitySteam Sterilizer Load Chart

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Flash 10+ (f10)	2	275°F (135°C)	10 min.	30 sec.[5]	• Unwrapped porous or non-porous single instrument • Unwrapped porous & non-porous instrument trays, up to 16 lbs (per tray).	1 2	1 2	1 2
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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)

http://www.fda.gov/cdrh/ode/INDICUSE.HTML

[signature]

[illegible] Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K070457