MAY 12 2003

510(k) SUMMARY

K031259

Model 833HC Vacuum/Gravity Steam Sterilizer

Submitted by:	Getinge Sourcing LLC 1777 E Henrietta Road Rochester, NY 14623-3133
Contact Person:	Frederick R. Catt Senior, Regulatory Engineer Phone: (585) 272-5013 Fax: (585) 272-5299
Date prepared:	April 18, 2003
Proprietary Name:	Model 833HC Vacuum/Gravity Steam Sterilizer
Common Name:	Steam Sterilizer
Device Classification:	Steam Sterilizer (80 FLE) Class II, as listed per 21 CFR 880.6880
Predicate Device:	Model 833HC Vacuum/Gravity Steam Sterilizer [K020590]

Description of Device:

The 833HC Vacuum/Gravity Steam Sterilizer is intended for use in hospital and health care facilities. The product incorporates a large sized chamber and has the same control system and offers similar overall features as those on the 733HC Vacuum/Gravity Steam Sterilizers. These include:

- additional functionality
- ease of use to the end user
- large color display that will allow the user to choose from the entire list of available cycles
- allows renaming and re-sequencing of sterilization cycles.

The full list of available cycles is as follows in Table 1:

Table 1. Model 833HC Vacuum/Gravity Steam Sterilizer Cycle and Load Chart

Cycle Type	Factory Set Cycle P#	Factory Settings			Load Configuration [2]	
		Exposure Temp.	Exposure Time	Dry Time [1]		
PREVAC1 (vac)	P1-P6	275°F (135°C)	3 min.	16 min.	Wrapped instrument trays, up to 16 lbs., per tray • 42" length – 12 max. • 76" length – 24 max.	Fabric packs • 42" length – 36 max. • 76" length – 72 max.
Bowie-Dick Test (vac)	P7	273°F (134°C)	3.5 min	0 min.	S.M.A.R.T. Pack or equivalent (1 max.)	
GRAVITY1 (grv)	P8-P10	250°F (121°C)	30 min.	30 min.	Wrapped instrument trays, up to 16 lbs., per tray • 42" length 12 max. • 76" length 24 max.	Fabric packs • 42" length 36 max. • 76" length 72 max.
GRAVITY2 (grv)	P11-P13	275°F (135°C)	10 min.	30 min.	Wrapped instrument trays, up to 16 lbs., per tray • 42" length 12 max. • 76" length 24 max.	Fabric packs • 42" length 36 max. • 76" length 72 max.
Vacuum Leak Test [3] (lkt)	P14	268°F (131°C)	3 min.	15 dry +5 dwell +15 test	Empty chamber	

Notes for Table 1:

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.
2. Refer to AAMI standards ST46 Good Hospital Practice: Steam Sterilization and Sterility Assurance.
3. Vacuum leak test cycle parameters are not adjustable.

Intended Use:

Model 833HC Vacuum/Gravity Steam Sterilizers are intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments and linens by means of pressurized steam.

Predicate Device

Model 733HC Vacuum/Gravity Steam Sterilizers [K020590].

Nonclinical Comparisons to Predicate Device

The 833HC Vacuum/Gravity Steam Sterilizer is a new model number designation to identify incorporation of our updated sterilizer control system (PACS 3000) with large sterilizer chamber sizes and loads. The chamber cross-section dimensions are 672mm x 920mm (26.5" x 36"). Two lengths are available – 1067mm (42"), and 1930mm (76"). The 833HC sterilizer is similar to the 733HC Steam Sterilizer (predicate device), but with a larger chamber size and volume. Modifications made from the predicate device include:

- The sterilizer chamber height and volumes are increased.
- The 833HC steam sterilizers can be either pit mounted (with the chamber floor level to the room floor) or floor mounted.
- Door movements were modified to include a door lift phase that accommodates for the increased door height and the need to lift the door from being below floor level, especially for pit mounted sterilizers.
- Flash and Liquids Cycles are not offered for this larger capacity sterilizer.
- Pipe routing changes were done to integrate with the larger pressure vessel design where some of the piping is routed to either the left or right side of the vessel, due to limited space beneath the vessel.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The 833HC Vacuum/Gravity Steam Sterilizer is a substantially equivalent device to that of the predicate device. There have been no substantial changes in technology, 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

MAY 12 2003

Mr. Frederick R. Catt
Senior, Regulatory Engineer
Getinge Sourcing LLC
1777 E Henrietta Road
Rochester, New York 14623-3133

Re: K031259
Trade/Device Name: Model 833HC Vaccuum/Gravity Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: April 18, 2003
Received: April 22, 2003

Dear Mr. Catt:

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 (301) 594-4618. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim 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 STATEMENT

510(k) Number: K031259

Device Name: **833HC Vacuum/Gravity Steam Sterilizer**

Indications for Use:

The Model 833HC Vacuum/Gravity Steam Sterilizer is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments and linens, by means of pressurized steam.

Table 1. Model 833HC Vacuum/Gravity Steam Sterilizer Cycle and Load Chart

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GRAVITY2 (grv)	P11-P13	275°F (135°C)	10 min.	30 min.	Wrapped instrument trays, up to 16 lbs., per tray • 42" length 12 max. • 76" length 24 max.	Fabric packs • 42" length 36 max. • 76" length 72 max.
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3. Vacuum leak test cycle parameters are not adjustable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number K031259