FEB 10 1998 K973225

510(k) SAFETY AND EFECTIVENESS SUMMARY

for

Castle Series 200 Steam Sterilizers (Powerclave)

Submitted by

Getinge/Castle, Inc.
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November 24, 1997

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Per 21 CFR 807.92(a)(1) & (a)

Per 21 CFR 807.92(a)(2)

This summary is for the:

Trade Name	Castle Series 200 Steam Sterilizers (Powerclave)
Common Name	Steam Sterilizer (greater than 2 cubic feet)
Classification Name	Steam Sterilizer (per 21 CFR 880.6880)

Per 21CFR 807.92(a)(3)

We believe this product to be substantially equivalent to our Castle Microcomputer Controls and Sterilizers K820783.

Per 21CFR 807.92(a)(4), (5) & (6)

The Castle Series 200 Sterilizers (Powerclave) is a control system upgrade of an existing microcomputer control system intended to be used with hospital steam sterilizers. Specifically, PACS 2000 controls applied to the Series 200 (Powerclave) Steam Sterilizer are to be used with "Castle" brand sterilizers manufactured by Getinge/Castle, Inc for use in health care facility environments. These sterilizers are intended to be used to sterilize wrapped and unwrapped surgical instruments, hard goods, and linens.

The difference between the predicate sterilizer controls and the PACS 2000 controls is that the PACS 2000 controls are provided with a more modern microprocessor, software, and an interactive operator interface. The piping remains relatively unchanged, with the addition of a chamber drain float switch to signal possible water-in-chamber conditions and a thermostatic drain discharge temperature control. A minor change on each chamber vessel size has changed the interior chamber width from 24 inches to 26 inches; the length on the mid-sized vessel has changed from 49 inches to 50 inches.

Per 21CFR 807.92(b)(1), (2) & (3)

The following standards were used to establish the minimum construction and performance requirements for this product:

ANSI/AAMI ST-8 - 1994 American National Standard for Hospital Steam Sterilizers,
CAN/CSA-Z314.7-M91 Effective Sterilization in Hospitals by the Steam Process (ref. AAMI ST8-1988),
GGS-1340A November 24, 1975 Federal Specification Sterilizer, Surgical Instrument and Supply Gravity Air Removal, Non-Portable (Heat and Moisture Stable),
GGS-1343A November 26, 1975 Federal Specification Sterilizer, Surgical Instrument and Supply Mechanical Air Removal, Non-Portable (Heat and Moisture Stable)

Evaluation studies consisting of fabric and instrument loads (wrapped and unwrapped) have been completed to validate the safety and effectiveness of the Series 200 Steam Sterilizer (Powerclave). The plan for this was derived from AAMI ST8 1994 and the accepted industrial standards listed above. Validation testing was performed using accepted half cycle analysis and results consistent with a sterility assurance level of at least 10^{-6} were obtained.

The cycles to be cleared for each of the models are listed in the following table:

Sterilizer Model	Cycle Type	Exposure Time Minutes*	Exposure Temperature	Drying Time Minutes	Loads
222	Gravity	30	250 °F	30	Wrapped Linen Packs
	Gravity	10	275 °F	30	Wrapped Hard Goods
	Gravity/Flash	3	275 °F	0	Unwrapped Nonporous Instruments
	Gravity/Flash	10	275 °F	0	Unwrapped Porous Instruments
223	Gravity	30	250 °F	30	Wrapped Linen Packs and Hard Goods
	Gravity	10	275 °F	30	Wrapped Hard and Dry Goods
233	Prevacuum	3	275 °F	16	Wrapped Hard and Dry Goods
	Prevacuum	3	275 °F	3	Linen Packs & Single Wrapped Hard Goods
	Gravity	30	250 °F	30	Wrapped Linen Packs and Hard Goods
	Bowie-Dick Test	3.5	273 °F	0	Air Removal Test Pack
	Air leak Test	3	268 °F	15	No Load - Vacuum Leak test

* Exposure times listed are actual times of the cycles to be cleared and are not half times.

This product has been also designed to meet the requirements of UL544 and CSA C22.2 N° 151 product safety standards for medical devices. The vessels are designed and constructed to Section VIII of the ASME pressure vessel code, and each vessel is so certified.

We believe the product to conform to the above requirements.

No clinical testing is required for this submittal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gettinge/Castle, Incorporated
C/O Mr. Gordon Gillerman
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

FEB 10 1998

Re: K973225
Trade Name: Castle Series 200 Steam Sterilizer (Straightline)
Regulatory Class: II
Product Code: FLE
Dated: February 2, 1998
Received: February 3, 1998

Dear Mr. Gillerman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K973225

Device Name: Castle Series 200 Steam Sterilizer (Powerclave)

Indications For Use: Indoor Use Only

Model 222:

The Castle Model 222 Gravity Steam Sterilizer is intended for steam sterilization of hospital supplies. Typical clinical (Hospital) applications include wrapped and unwrapped hard goods and linens.

Wrapped-goods cycles are provided for processing wrapped linen packs, as well as wrapped hard goods such as instruments and utensils. Unwrapped goods cycles (flash) are used to process unwrapped hard goods such as instruments and utensils. Steam sterilization by the unwrapped (flash) method is employed when time does not permit the use of the preferable, wrapped sterilization procedure. Implantables should never be sterilized by the unwrapped (flash) method. All cycles employ gravity or downward displacement with positive pulsing conditioning for dynamic air removal. Processing temperatures range from 250°F to 275°F (121°C to 135°C)

The cycles to be cleared for this model (**Model 222**) are:

Cycle	Name	Type	Exposure Temp	Exposure Minutes	Dry Minutes
P1	GRAV WRAP 1	Gravity 250°F	250°F	30	30
P2	GRAV WRAP 2	Gravity 275°F	275°F	10	30
P3	FLASH 3 +	Gravity 3 Minutes	275°F	3	0
P4	FLASH 10 +	Gravity 10 Minutes	275°F	10	0

Model 233:

The Castle Model 233 Vacuum Steam Sterilizer is intended for steam sterilization of hospital supplies. Typical clinical (Hospital) applications include wrapped hard goods and linens.

Wrapped-goods (Hi Vac) cycles are provided for processing wrapped linen packs, as well as wrapped hard goods such as instruments and utensils. A gravity cycle is provided for processing wrapped dry goods and/or hard goods. Additionally, a Vacuum Leak Test cycle, not intended for sterilization, and an Air-Removal-Test-Pack (Bowie-Dick) cycle, not intended for sterilization is provided. The wrapped-goods (Hi Vac) cycles employ vacuum-and-positive pulsing to condition a load before processing at the selected exposure temperature. The gravity cycle employs the gravity, or downward displacement method of air removal. Processing temperatures for wrapped goods cycles range from 250°F to 275°F (121°C to 135°C).

The cycles to be cleared for this model (**Model 233**) are:

Cycle	Name	Type	Exposure Temp	Exposure Minutes	Dry Minutes
P1	PREVAC ONE	Prevac 275°F	275°F	3	16
P2	PREVAC TWO	Prevac 275°F	275°F	3	3
P3	GRAVITY WRAP	Gravity 250°F	250°F	30	30
P5	B-D TEST	Air Removal	273°F	3.5	0
P6	VAC LEAK TST	Vacuum Leak	268°F	3	15(dry)+5(dwell)+15(test)

Model 223:

The Castle Model 223 Gravity Steam Sterilizer is intended for steam sterilization of hospital supplies. Typical clinical (Hospital) applications include wrapped and unwrapped hard goods and linens.

Wrapped-goods cycles are provided for processing wrapped linen packs, as well as wrapped hard goods such as instruments and utensils. The cycles employ gravity or downward displacement with positive pulsing conditioning for dynamic air removal. Processing temperatures for wrapped goods cycles range from 250°F to 275°F (121°C to 135°C).

The cycles to be cleared for this model (**Model 223**) are:

Cycle	Name	Type	Exposure Temp	Exposure Minutes	Dry Minutes
P1	GRAV WRAP 1	Gravity 250°F	250°F	30	30
P2	GRAV WRAP 2	Gravity 275°F	275°F	10	30

All Models:

Castle Series 200 Steam Sterilizers are programmed with factory recommended sterilization parameters (cycle settings) which have been verified and validated for efficacy. By using a supervisory password, the controls allow for flexibility in selecting exposure temperature, exposure time, and drying time. It is possible, with that password, to select cycle settings that will not necessarily achieve the desired sterility assurance level. Users with password access are responsible for the efficacy of any cycle settings other than the factory recommended settings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973225

Prescription Use_____ OR **Over-The Counter Use** X
(Per 21 CFR 801.109)