

Per 21 CFR 807.92(a)(2)

NOV 12 1997

This summary is for the:

Trade Name	Castle Series 100 Steam Sterilizers (Straightline)
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 Contros and Sterilizers K820783.

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

The Castle Series 100 Sterilizers (Straightline) is an upgrade of an existing microcomputer control system intended to be used with hospital steam sterilizers. Specifically, PACS 2000 controls applied to the Series 100 (Straightline) Steam Sterilizer are to be used with "Castle" brand sterilizers manufactured by Getinge/Castle, Inc. for use in industrial, laboratory, and health care facility environments. These sterilizers are intended to be used to sterilize wrapped and unwrapped surgical instruments, linens and liquids (liquids not intended for direct patient contact)

The difference between predicate sterilizer controls and the PACS 2000 controls is that the PACS 2000 controls are provided with more modern microprocessor/software, and interactive operator interface. The chamber vessel and piping remain unchanged.

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

The ANSI/AAMI ST-8 - 1994 American National Standard for Hospital Steam Sterilizers, AAMI ST37-1996 Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use, CAN/CSA-Z314.7-M91 Effective Sterilization in Hospitals by the Steam Process (ref. AAMI ST8-1988), GG-1340A November 24, 1975 Federal Specification Sterilizer, Surgical Instrument and Supply Gravity Air Removal, Non-Portable (Heat and Moisture Stable) was used to establish the minimum construction and performance requirements for this product.

Evaluation studies consisting of fabric and instrument loads (wrapped and unwrapped) have been completed to validate the safety and effectiveness of the Series 100 Steam Sterilizer (Straightline). 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 cleared for each of the models are listed in the following table:

Sterilizer Model	Cycle Type	Exposure Time	Exposure Time*	Drying Time	Loads
122	Gravity	30	250	30	Wrapped Linen Packs
	Gravity	10	275	30	Wrapped Hard Goods
	Gravity/Flash	3	275	0	Unwrapped Nonporous Instruments
	Gravity/Flash	10	275	0	Unwrapped Porous Instruments
123	Gravity Cycle	30	250	30	Wrapped Linen Packs and Hard Goods
	Gravity/Flash	3	275	0	Unwrapped Nonporous Instruments
133	Prevacuum	3	275	16	Wrapped Hard Goods
	Prevacuum	3	275	3	Linen Packs & Single Wrapped Hard Goods
	Gravity/Flash	3	275	0	Unwrapped Nonporous Instruments
	Gravity/Flash	10	275	0	Unwrapped Porous Instruments
	Air leak Test	3	268	15	No Load - Vacuum Leak test

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

This product has been also designed to meet the requirements of UL544 and CSA C22.2 No. 151 product safety standards for medical devices. The vessel 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1997

Mr. Michael J. Palladino
Getinge/Castle, Incorporated
C/O MET Laboratories
914 West Patapsco Avenue
Baltimore, Maryland 21230-3432

Re: K970907
Trade Name: Castle Series 100 Steam Sterilizers
(Straightline)
Regulatory Class: II
Product Code: FLE
Dated: October 28, 1997
Received: October 29, 1997

Dear Mr. Palladino:

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.

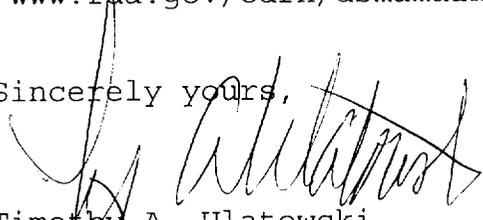
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

K9 10907/A1

510(k) Number (if Known): _____

Device Name: Castle Series 100 Steam Sterilizer (Straightline)

Indications For Use:

The Getinge/Castle Series 100 Steam Sterilizers (Straightline) with the PACS 2000 controls is an upgrade of an existing microcomputer control system for a comprehensive line of health care reusable medical reprocessing equipment. The PACS 2000 controls are intended to be used for the control of a variety of equipment including washers, washing/disinfectors, washer/sterilizers and sterilizers. This submittal is made for the PACS 2000 controls applied to the Getinge/Castle (Straightline) line of steam sterilizer models (see attachment Section 18 - Competitive Comparison). The Series 100 (Straightline) sterilizer line includes two sizes, A 16" x 16" x 26" chamber having a volume 3.9 cubic feet and a 20" x 20" x 38" chamber having a volume 8.8 cubic feet. Both chamber sizes include single and double door sterilizers with a power door offered on the single door model only. The Series 100 Steam Sterilizer (Straightline) includes gravity (Model 122) and prevacuum (Model 133) steam sterilizers for healthcare facilities and moist heat (Model 123) sterilizes for laboratories and industrial uses. The latter applications are addressed in this submittal for the rare occasion health care facilities may use them. The to be cleared for each of the models are as follows:

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For the Model 122

- P1 - GRAV WRAP 1 - Gravity Cycle - 30 minute exposure at 250°F and 30 minute dry
- P2 - GRAV WRAP 2 - Gravity Cycle - 10 minute exposure at 275°F and 30 minute dry
- P3 - FLASH 3+ - Gravity Cycle with 3 minute exposure at 275°F and 0 minute dry
- P4 - FLASH 10+ - Gravity Cycle with 10 minute exposure at 275°F and 0 minute dry

For the Model 123

- P1 - GRAV WRAP 1 - Gravity Cycle - 30 minute exposure at 250°F and 30 minute dry
- P4 - FLASH 3+ - Gravity Cycle - 3 minute exposure at 275°F and 0 minutes dry

For the Model 133

- P1 - PREVA WRAP - Prevacuum Cycle - 3 minute exposure at 275°F and 16 minute dry
- P2 - PREVA WRP1 - Prevacuum Cycle - 3 minute exposure at 275°F and 3 minute dry
- P3 - FLASH 3+ - Gravity Cycle - 3 minute exposure at 275°F and 0 minute dry
- P4 - FLASH 10+ - Gravity Cycle - 10 minute exposure at 275°F and 0 minute dry
- P5 - VAC LEAK TST - Air leak Test - 3 minute exposure at 268°F and 15 min. leak test

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

(Division Sign-Off) Concurrency of CDRH, Office of Device Evaluation (ODE)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____

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