 FEB 16 2000 K994314

510(k) SUMMARY

Castle® Series 100HC Steam Sterilizers

Submitted by: Getinge/Castle Inc.
1777 E Henrietta Road
Rochester, NY 14623-3133

Contact Person: Frederick R. Catt
Senior, Regulatory Affairs and Code Compliance Engineer
Phone: (716) 272-5013
Fax: (716) 272-5299

Date prepared: January 25, 2000

Proprietary Name: Castle® Series 100HC Steam Sterilizers

Common Name: Steam Sterilizer

Device Classification: Steam Sterilizer (80FLE)

Class II, as listed under Title 21 CFR 880.6880

Predicate Device: Castle® Series 100 Steam Sterilizers (Straightline) [K970907]

Description of Device:

The 100HC Steam Sterilizers represent a series of sterilizers intended for use in hospital and health care facilities. The product provides an update to the control system that provides additional functionality and ease of use to the end user that includes the added flexibility to adjust cycle parameters (as on previous sterilizer models), rename, and reassign (re-sequence) the designated sterilization cycles.

(continued....)

Full List of Available Cycles for Series 100HC - up to 19 Total Cycles (w/ P1 - P6 Active)

Ref. No.	Cycle Type	Exposure Temperature [°F/°C]	Exposure Time [Min.]	Drying Time [Min.]	Available and Factory Set P# Cycles [122HC]	Available and Factory Set P# Cycles [133HC]	Load Configuration
1	Gravity 1	250/121	30	30	P1	Available	• Double Wrapped Instrument Trays, 16lbs. (2 max.) • Fabric Packs (2 max. in 16"x16" chamber) (12 max. in 20"x20" chamber)
2	Gravity 1	250/121	30	30	Available	Available	
3	Gravity 2	275/135	10	30	P2	Available	
4	Gravity 2	275/135	10	30	Available	Available	
5	Liquids 1*	250/121	30	0.75psi/min.	Available	Available	• Up to 250 mL Containers (40 max. in16" chamber) (168 max. in 20" chamber)
6	Liquids 2*	250/121	45	0.75psi/min.	Available	Available	• Up to 1000 mL Containers (15 max. in 16" chamber) (32 max. in 20" chamber)
7	Flash 3+	275/135	3	0	P3	Available	• Unwrapped Single Instrument • Unwrapped Non-Porous Instrument Trays up to 16lbs. (2 max.)
8	Flash 3+	275/135	3	0	P4	P3	
9	Flash 3+	275/135	3	0	Available	Available	
10	Flash 3+	275/135	3	0	Available	Available	
11	Flash 10+	275/135	10	0	P5	P4	• Unwrapped Single Instrument • Unwrapped Porous and Non-Porous Instrument Trays up to 16lbs. (2 max.)
12	Flash 10+	275/135	10	0	P6	Available	
13	Flash 10+	275/135	10	0	Available	Available	
14	Flash 10+	275/135	10	0	Available	Available	
15	Prevacuum 1	275/135	3	16	NA	P1	• Double Wrapped Instrument Trays 16lbs. (2 max.) • Fabric Packs (2 max. in 16"x16" chamber) (12 max. in 20"x20" chamber)
16	Prevacuum 2	275/135	3	3	NA	P2	• Single Wrapped Single Instrument • Single Wrapped Instrument Trays 16lbs. (2 max.) • Fabric Packs (2 max. in 16"x16" chamber) (12 max. in 20"x20" chamber)
17	Prevacuum 2	275/135	3	3	NA	Available	
18	Bowie-Dick Test	273/134	3.5	0	NA	P5	• S.M.A.R.T. Pack (Bowie-Dick Pack.) (1 max.)
19	Leak Test	268/131	3	15/5/15**	NA	P6	• Empty Chamber Test

Note 1: Qualified Getinge/Castle personnel may reassign (re-sequence) "Available" cycles to P1-P6.

Note 2: Load configurations are based on AAMI ST8, ST37 & ST46 Standards and Guidelines.

Note 3: *The Liquids cycle is not intended for the sterilization of liquids intended for direct patient contact. Liquid cycles have 8 minute liquid dwell time as factory set parameter and indicated dry time is slow exhaust rate.

Note 4: **15 minute dry, 5 minute dwell, 15 minute timed vacuum leak rate test for change in pressure (differential).

NA: Cycle Not Available

Intended Use:

Castle® Series 100HC Steam Sterilizers are 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.

(continued...)

Predicate Device

Castle® Series 100 Steam Sterilizer (Straightline) [K970907].

Nonclinical Comparisons to Predicate Devices

Castle® Series 100HC Steam Sterilizers is a new model designation to identify incorporation of design improvements. These sterilizers are very similar to the Series 100 Steam Sterilizers (predicate device). Modifications made to the predicate device include:

- Addition of the "HC" suffix (Health Care facility type intended use)
- Software change to provide a more modular structure
- Customer ability to select, from 19 pre-validated cycles, the cycles to be configured by a qualified Getinge/Castle representative for the P1 – P6 control settings
- Ability for qualified Getinge/Castle representatives to modify a customized cycle description (up to 8 digits) in addition to the fixed cycle type designation for the P1 – P6 control settings
- Customer ability for user to modify cycle parameters (time and temperature), through password access, to accommodate specific device sterilization cycle requirements
- Selectable temperature (°F or °C) and pressure (psi, kPa, or bars) units
- Minor piping changes to accommodate manufacturing
- Adjustments to password features
- Power door option made available for double door vessels
- Power failure and recovery times lengthened

Clinical Data:

No clinical data is required for this submission.

Conclusion:

Castle® Series 100HC Steam Sterilizers provide substantially equivalent product as those of our predicate device. There have been no substantial changes in technology, intended use, or labeling of this device. The sterilizers meet the applicable requirements of AAMI ST8, CSA-Z314.7, and GGS-1340A standards.

Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate devices 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

FEB 16 2000

Mr. Mark N. Smith, P.E.
Director
Regulatory Affairs/Quality Assurance
Getinge/Castle, Incorporated
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K994314
Trade Name: Castle® Series 100HC Steam Sterilizers
Regulatory Class: II
Product Code: FLE
Dated: January 25, 2000
Received: January 27, 2000

Dear Mr. Smith:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

INDICATIONS FOR USE STATEMENT

510(k) Number: K994314

Device Name: **Castle® Series 100HC Steam Sterilizers**

Indications for Use:

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Full List of Available Cycles for Series 100HC - up to 19 Total Cycles (w/ P1 - P6 Active)

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12	Flash 10+	275/135	10	0	P6	Available	
13	Flash 10+	275/135	10	0	Available	Available	
14	Flash 10+	275/135	10	0	Available	Available	
15	Prevacuum 1	275/135	3	16	NA	P1	Double Wrapped Instrument Trays 16lbs. (2 max.) Fabric Packs (2 max. in 16"x16" chamber) (12 max. in 20"x20" chamber)
16	Prevacuum 2	275/135	3	3	NA	P2	Single Wrapped Single Instrument Single Wrapped Instrument Trays 16lbs. (2 max.) Fabric Packs (2 max. in 16"x16" chamber) (12 max. in 20"x20" chamber)
17	Prevacuum 2	275/135	3	3	NA	Available	
18	Bowie-Dick Test	273/134	3.5	0	NA	P5	S.M.A.R.T. Pack (Bowie-Dick Pack.) (1 max.)
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Note 4: **15 minute dry, 5 minute dwell, 15 minute timed vacuum leak rate test for change in pressure (differential).

NA: Cycle Not Available

(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 K994314

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