DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Getinge Sourcing, LLC
Barb Smith
Sr. Regulatory Affairs Specialist
1777 East Henrietta Road
Rochester, New York 14623

June 3, 2016

Re: K153713
Trade/Device Name: Getinge Series Warming Cabinet
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: LHC
Dated: December 21, 2015
Received: December 24, 2015

Dear Barb Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153713

Device Name
Getinge Series Warming Cabinet models 5524, 5618, 5624

Indications for Use *(Describe)*
Getinge Series Warming Cabinet (models 5524, 5618, 5624) are designed for the heating and storage of irrigation solutions and/or blankets used in the care of patients in areas such as surgery, recovery, OB/GYN, ICU or ER.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Getinge Series Warming Cabinet

K153713

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

Contact Person: Barb Smith, RAC
Sr. Regulatory Affairs Specialist
Phone: (585) 214-6049
Fax: (585) 272-5299

Date prepared: June 7, 2016

Proprietary Name: Getinge Series Warming Cabinet

Common Name: Warmer, Irrigation Solution

Device Classification: Unclassified

Predicate Device: AMSCO Warming Cabinet [K092823]

Description of Device:

The Getinge Series Warming Cabinets are designed for warm storage of solutions and blankets used for patient care in healthcare facilities. The model designations include 5618, 5624, and 5524. The Getinge Series Warming cabinet is not intended for the storage of injectable fluids, blood or blood products.

Intended Use:

The Getinge Series Warming Cabinet is intended for use by health care facilities for warm storage of irrigation solutions and blankets used for patient care.

Comparisons to Predicate Device:

Similarities between the Getinge Series Warming Cabinet and the identified predicate are:

- Intended use is similar: Intended for use by health care facilities to warm blankets and solutions used in patient care. Getinge models are not intended for the storage of injectable fluids.

- Operating Principle is the same: Electric heater and fan blowing (convection heating).

- Materials of construction are the same (stainless steel). There is no direct patient contact associated with this device.

- Temperature Selection: Same; 32°C - 71°C (90°F - 160°F)

- Both have over temperature alarms and temperature lockout functions

The primary difference between the Getinge Series Warming Cabinet and the predicate device (AMSCO Warming Cabinet) is that the Getinge Series Warming Cabinet is not labeled for the storage of injectable fluids.

Comparison Matrix Getinge Series Warming Cabinet to Predicate Device

#	Features	Getinge Series Warming Cabinet [Subject Device]	AMSCO K092823 [Predicate Device]	Comparison
1	Intended Use	Designed for the warm storage of the solutions and blankets used for patient care in Healthcare facilities.	Designed to raise the temperature of blankets, linens and sterile surgical irrigation solutions and IV solutions to an acceptable level for various surgical, obstetrical, emergency, critical care and other healthcare applications. The Amsco Warming Cabinet is designed to hold a combination of flasks and/or dry goods.	Same with exception of IV fluids
2	Heating System	Electric heater and fan blowing (convection heating)	Electric heater and fan blowing (convection heating)	same
3	Unit Configuration	Single/Double	Single/Double	same
4	Unit Depth	18” or 24”	18” or 24”	same
5	Model	Wall or Counter	Wall or Counter	same
6	Interior and Exterior Surfaces	Stainless steel and glass	Stainless Steel, ABS Plastic and laminated galvanized steel	Same and similar materials
7	Installation	Free standing with pedestal base, recessed, wall mounted cabinet	Free Standing (mobile) or recessed	Same with exception of mobile free standing unit
8	Door	Tempered glass framed with stainless steel	Stainless Steel (Solid and Glass)	same
9	Cabinet Storage Capacity	Model 5524 = 4.1 cu ft – up to 30 (1 liter) bottles Model 5618 upper chamber = 2.9 cu ft – up to 18 (1 liter) bottles	18” upper/single = 3.2 cu ft – up to 24 (1 liter) bottles 18” lower chamber = 8.5 cu ft – up to 72 (1 liter) bottles 24” upper/single = 4.3 cu ft –	Smaller capacity in some models

#	Features	Getinge Series Warming Cabinet [Subject Device]	AMSCO K092823 [Predicate Device]	Comparison
		Model 5618 lower chamber = 10.0 cu ft – up to 48 (1 liter) bottles Model 5624 upper chamber = 4.1 cu ft – up to 30 (1 liter) bottles Model 5624 lower chamber = 13.7 cu ft – up to 60 (1 liter) bottles	up to 30 (1 liter) bottles 24" lower chamber = 11.6 cu ft – up to 90 (1 liter bottles)	
10	Cabinet Volume	Model 5524 = 4.1 cu ft Model 5618 upper chamber = 2.9 cu ft Model 5618 lower chamber = 10.0 cu ft Model 5624 upper chamber = 4.1 cu ft Model 5624 lower chamber = 13.7 cu ft	18" upper chamber = 3.1 cu ft 24" upper chamber = 4.2.cu ft 18" lower chamber = 8.9 cu ft 24" lower chamber = 12 cu ft	Smaller cabinet volume in some models
11	Controls	Push button keypad controls : control on/off/, temperature set point, temperature display in °F or °C, temperature set point "lock in" LED display provides: controls off, chamber temperature, power loss, temperature set point, overheat, set point lock/unlock, heater on, Fahrenheit or Celsius. An audible alarm indicates overheat condition.	Digital push button keypad/power switch/Digital LCD temperature display/mode selection buttons/door ajar indicator/Over-temperature light for each compartment/Data port for retrieval of stored temperatures	Same with exception of data port for retrieval of stored temperatures
12	Software	Unit contains software	Unit contains software	same
13	Temperature Selection Range	32°C (90°F) to 71°C (160°F)	90°F (32°C) to 160°F (71°C)	same
14	Temperature Lock	Temperature lock-out function to prevent unauthorized temperature changes.	Temperature lock-out function to prevent unauthorized temperature changes.	same
15	Door Lock	none	Manual mechanical door lock or optional electronic door lock system for each compartment	Door lock not available on subject device
16	Over Temperature Alarm Point	In the event that chamber temperature exceeds the selected temperature by 4°C (7°F) an "OH" (representing	Visual and audible alarm if unit has a chamber temperature greater than 10°F (5.5°C) above set temperature. In the	Same alarm functions. Subject device alarms at a lower

#	Features	Getinge Series Warming Cabinet [Subject Device]	AMSCO K092823 [Predicate Device]	Comparison
		overheat) is displayed, an alarm sounds and power to the heaters is shut off.	event of an over temp condition, sensors automatically turns off the heater(s).	overtemp condition.
17	Voltage Requirements	110/220 Vac, 220/240 VAC nominal, 50/60 HZ	110/220 Vac, 220/240 VAC nominal, 50/60 HZ	same

Summary of Performance Testing:

Performance testing was conducted to provide evidence that the Getinge Series Warming Cabinet performs as intended. Testing included empty chamber temperature profiles, heat up time with loads and testing of controls including overheat alarm conditions. Testing included 3rd party tests to verify compliance to IEC 61010-1, 61010-2-010 and 61326-1 for electrical safety and EMC requirements. All tests were conducted on current production units. The results of the testing demonstrate that the Getinge Series Warming Cabinet performs as intended.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The Getinge Series Warming Cabinet has the same intended use and technological characteristics as the predicate device. The Getinge Series Warming Cabinet has been tested and shown to meet the requirements of the product specification and intended use. Based on the information provided in this premarket notification, it can be concluded that the subject device is substantially equivalent to the predicate device.