K094026
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Section 5 – 510(k) Summary

JUL 12 2011

Device Owner and Manufacturer

CPAC, Inc

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Contact person

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Summary prepared on December 23, 2009

Device

Trade name: Steri-Dent Model 2100/3100

Common name: Table Top Dry Heat Sterilizer

Classification name: Sterilizer, Dry Heat (21 CFR 880.6870, Product Code KMH)

Predicate Device

The Steri-Dent Model 2100 and 3100 are substantially equivalent to the Steri-Dent Model 200 and 300 both of which are table top dry heat sterilizers currently manufactured by CPAC, Inc and legally marketed under 510(k) K771070.

Device Description

The Model 2100 and 3100 are table-top natural convective (static air type) dry heat sterilizers designed for use in healthcare facilities for the sterilization of wrapped and unwrapped metal instruments and glassware. The single sterilization cycle runs at 160°C (320°F) for 1 hour (60 minutes). Items to be sterilized are placed horizontally on the removable trays inside the chamber.

Both models are plug-in units designed to run on standard 115 VAC household current. A thermocouple is used to measure the chamber temperature. All functions of the sterilizer are controlled by an embedded PCB. Access to the heating chamber is through a hinged door on the front of unit. A LED digital display located on the front of the unit indicates chamber temperature and remaining cycle time.

Indications for Use

The Model 2100 and 3100 are table-top natural convective (static air type) dry heat sterilizers designed for use in healthcare facilities for the sterilization of wrapped and unwrapped metal instruments and glassware. The single sterilization cycle runs at 160°C (320°F) for 1 hour (60 minutes).

The Model 2100 and 3100 are identical in operation and only differ in instrument capacity. The Model 2100 is provided with two (2) trays and the Model 3100 is provided with three (3) trays that are slightly larger in size than the Model 2100 trays. The maximum recommended load for each tray for the Model 2100 is 1.3 lbs including the weight of the tray. For the Model 3100, the maximum recommended load for each tray is 1.4 lbs including the weight of the tray.

The indications for use are the same for the predicate device.

Technological Characteristics Comparison

Below is a comparison of the technological characteristics of the two (2) tray sterilizers, Models 200 and 2100, and also the three (3) tray sterilizers, Models 300 and 3100.

Characteristic	Predicate Device – Model 200	Device – Model 2100
Method of Organism Destruction	Dry heat (static air)	Dry heat (static air)
Method of heating	Electric element	Electric element
Sterilizing temperature	320°F	320°F
Sterilizing cycle time	60 minutes	60 minutes
Chamber Size	12-1/4" x 7-15/16" x 5-3/8"	12-1/4" x 7-15/16" x 5-3/8"
Tray Capacity	(2) 9-1/2" x 6-3/8" x 1/2" Trays	(2) 9-1/2" x 6-3/8" x 1/2" Trays
Total Heater Wattage	500W	500W
Load capacity	1.3 pounds per tray (including weight of tray)	1.3 pounds per tray (including weight of tray)
Timer	Mechanical	Digital
Temperature Control	Bi-Metal Thermostat	Thermocouple with Electronic Control
Temperature monitoring	Spirit-filled thermometer	LED display
Process error detection	No	Yes, software monitors all cycle parameters and provides diagnostic error codes and audible alarm
User Option Interface	No	Yes, options such as unit of measure and use of audible alarm can be set by the user
Printer output	No	Yes

Technological Characteristics Comparison(cont)

Characteristic	Predicate Device – Model 300	Device – Model 3100
Method of Organism Destruction	Dry heat (static air)	Dry heat (static air)
Method of heating	Electric element	Electric element
Sterilizing temperature	320°F	320°F
Sterilizing cycle time	60 minutes	60 minutes
Chamber Size	14-7/8" x 9-1/16" x 7-3/8"	14-7/8" x 9-1/16" x 7-3/8"
Tray Capacity	(3) 12" x 7-3/8" x ½" Trays	(3) 12" x 7-3/8" x ½" Trays
Total Heater Wattage	735W	735W
Load capacity	1.4 pounds per tray (including weight of tray)	1.4 pounds per tray (including weight of tray)
Timer	Mechanical	Digital
Temperature Control	Bi-Metal Thermostat	Thermocouple with Electronic Control
Temperature monitoring	Spirit-filled thermometer	LED display
Process error detection	No	Yes, software monitors all cycle parameters and provides diagnostic error codes and audible alarm
User Option Interface	No	Yes, options such as unit of measure and use of audible alarm can be set by the user
Printer output	No	Yes

Non-Clinical Performance Data

Safety

Models 2100 and 3100 (115V only) have been tested, investigated and found to comply with the following standards:

- ANSI/UL 61010-1: Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1 – General Requirements
- CAN/CSA C22.2 No. 61010-1: Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1 – General Requirements
- IEC 61010-2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials

Non-Clinical Performance Data(cont)

Effectiveness

Thermal profile and sterile efficacy studies, following AAMI ST50 were performed by SPS Medical on the Model 2100 and 3100 sterilizers. These tests conclude that each sterilizer consistently provide a 12-log reduction of the *Bacillus atrophaeus* spores and produce a 10^{-6} SAL (Sterility Assurance Level).

The thermal profile tests for each sterilizer were run three times using a small load and three times using a full load in order to demonstrate that each sterilizer was able to consistently achieve and maintain the proper temperature inside the chamber. The thermal profiles revealed that the top tray of both sterilizers was the cold spot.

The sterile efficacy studies for the Model 2100 and 3100 sterilizers used the half-cycle overkill method to prove that the sterilizers recommended full cycle (160°C for 60 minutes) has a 10^{-6} SAL (Sterility Assurance Level) as required by AAMI ST50. Three full load half-cycle (30 minute) tests were run on each model. Testing demonstrated that the F_H values exceed the minimum of 30 minutes as required in AAMI ST50 for all test cycles. As outlined in AAMI ST50, multiple inoculated instruments including lumen devices and BI (biological indicator) strips were challenged in the sterilizers' cold spot. All 84 test samples were negative for growth and the positive controls were positive for growth. The performance testing validates the Model 2100 and 3100 are safe and effective sterilizers.

Test Results Conclusions

The Model 2100 and 3100 were found to comply with the latest safety standards which are the same standards that the predicate device has been found to comply.

The tests to ensure effectiveness of the Model 2100 and 3100 sterilizers were based on the latest AAMI ST50 standard and so were more stringent than those conducted on the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 12 2011

Re: K094026
Trade/Device Name: Steri-Dent Model 2100 and 3100
Regulation Number: 21 CFR 880.6870
Regulation Name: Dry-Heat Sterilizer
Regulatory Class: II
Product Code: KMH
Dated: July 5, 2011
Received: July 6, 2011

Dear Mr. Crane:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

501(k) Number: K094026

Device Name: Steri-Dent Model 2100 and 3100

Indications for Use

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Prescription Use_____ AND/OR Over-The-Counter Use___XX___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY),

Concurrence of CDRH, Office of Device Evaluation (ODE)

ivision Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

0(k) Number: K094026