K091685

510(k) Summary for the Kimberly-Clark* Corporation KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap for the Additional Indication for Use with Pre-Vacuum Steam

Date Summary was Prepared: June 5, 2009

510(k) Submitter:

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Device Common Name: Sterilization Wrap

Classification Name: Sterilization Wrap (21 CFR 880.6850)

Product Code: FRG

Intended Use: The KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by pre-vacuum steam at 270°F/132°C for 4 minutes. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened. The KC300 Model ONE-STEP* wrap was validated for dry times for pre-vacuum steam sterilization of 30 minutes.

KIMGUARD ONE-STEP* Sterilization Wrap is not indicated for use for gravity steam sterilization.

The KC 300 Model KIMGUARD ONE-STEP* Sterilization Wrap was previously cleared for use in K082177 for use with an ethylene oxide sterilization method of 100% ethylene oxide (EtO) with a concentration of 725-735 mg/L at 131°F/ 55°C and 40% - 80% relative humidity for 60 minutes.

See KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap recommendations for pre-vacuum steam on Page 2.

Predicate Devices:

The KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap for pre-vacuum steam sterilization is substantially equivalent to the predicate KIMGUARD ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600) (K082177).

Substantial Equivalence:

The KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap is identical to the predicate KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap in K082177 in design, materials, and intended use (the intended use is being expanded in this 510(k) notification to include pre-vacuum steam sterilization in addition to the previously cleared indication for use with ethylene oxide sterilization). The KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap is comprised of two sheets of KIMGUARD* Sterilization Wrap ultrasonically seamed on two sides. This allows for convenient wrapping with two sheets simultaneously. The sheets of sterilization wrap are square or rectangular fabric produced using a polypropylene three-layer SMS (spunbond-meltblown-spunbond) process.

Summary of Testing:

The KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap performance has been tested in accordance with the applicable requirements recommended in *Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA* (March 7, 2002). Testing included biocompatibility (i.e., irritation and sensitization) in compliance with the methods of ISO 10993, sterilant penetration, dry time, and physical integrity. The Wrap has also been tested for the ability to maintain sterility of pack contents after sterilization for up to 30 days under standard conditions. All results of testing met acceptance criteria.

KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap Recommendations for Pre-Vacuum Steam Sterilization[1]

KIMGUARD ONE-STEP* Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
KC300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs	15 huck towels (17"x 29") 1 small fluid resistant drape (60"x 76") 5 lbs of metal mass

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the KIMGUARD Sterilization Wraps (i.e.: the number and size of the fluid resistant linens or the weight of the metal mass).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Thomas Kozma
Director of Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

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Re: K091685
Trade/Device Name: KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap for the Additional Indication for Use with Pre-Vacuum Steam
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: June 5, 2009
Received: June 12, 2009

Dear Mr. Kozma:

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.

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/CDRH Offices/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 for

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap for the Additional Indication for Use with Pre-Vacuum Steam

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 091685

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____