K082177

510(k) Summary for the Kimberly-Clark* Corporation KIMGUARD ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)

Date Summary was Prepared: March 26, 2009

MAR 2 7 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: 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 or by 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. 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 wrap was validated for aeration times for EO sterilization of 8 hours at 55 °C or 12 hours at 43.3 °C. The wrap was validated for dry times for pre-vacuum steam sterilization of 20 minutes for Models 100 and 200, and for 30 minutes for Models 400, 500, and 600.

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

The KC300 Model KIMGUARD ONE-STEP Sterilization Wrap is not indicated for use for pre-vacuum steam sterilization.

See Wrap Model Recommendations on Page 3.

Predicate Devices:

The KIMGUARD ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600) are substantially equivalent to the predicate KIMGUARD* Regular and Heavy Duty Sterile Wraps (K881471)

Substantial Equivalence:

The KIMGUARD ONE-STEP* Sterilization Wrap is substantially equivalent to the predicates in intended use, design, and materials. The predicate devices were constructed of a three-layer laminate composed of a layer of meltblown polypropylene bonded on both surfaces with a layer of spunbonded polypropylene. The 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:

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.

Wrap Model Recommendations[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]
KC100	Very Light Weight Package (for example: towel packs)	3 lbs	16 huck towels (17"x 29")
KC200	Light Weight Package (for example: standard linen packs)	6 lbs	2 huck towels (17"x 29") 2 fluid resistant U-drape (68"x109") 1 fluid resistant universal bar drape (70" x 108")
KC300[3]	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs	FOR EO: 16 huck towels 2 fluid resistant large drapes (76"x100") 1 fluid resistant small drape (76"x60") 1 fluid resistant table cover (60"x 90")
KC400[4]	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs	4 tray liners 20" x 25" stacked 10" x 10" x 3 ½ " tray containing 11 lbs of metal mass
KC500[4]	Heavyweight Package (for example: general use medical instruments)	17 lbs	4 tray liners 20" x 25" stacked 10" x 10" x 3 ½ " tray containing 15 lbs of metal mass
KC600[4]	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs	4 tray liners 20" x 25" stacked 10" x 10" x 3 ½ " tray containing 23 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).

[3] The KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap is not indicated for use for pre-vacuum steam sterilization.

[4] The KC400, KC500, and KC600 model wraps were validated for sterilant penetration with 3 lbs of non-fluid resistant linen, and it is recommended to not exceed 3 lbs of non-fluid resistant linen in sterilization cycles with these models. It is recommended that the user not include fluid-resistant linens in KC400, KC500, and KC600 model wraps, as use of such fluid resistant materials has not been evaluated with these models.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2009

Kimberly-Clark Corporation
C/o Ms. Lisa Peacock, RAC
SciMed, Incorporated
172 Conductor Drive
Dawsonville, Georgia 30534

Re: K082177
Trade/Device Name: KIMGUARD ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: March 9, 2009
Received: March 10, 2009

Dear Ms. Peacock:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Antonio D. Watson for

Ginette Y. Michaud, M.D.
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): K082177

Device Name: KIMGUARD ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)

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The KC300 Model KIMGUARD ONE-STEP Sterilization Wrap is not indicated for use for pre-vacuum steam sterilization.

See Wrap Model Recommendations on Page 2.

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)

Mark N. Murphy D

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

510(k) Number: K082177

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