510(k) Summary

K141071

JUL 28 2014

Applicant's Name, Address, Telephone, FAX, Contact Person

Applicant Name: Kimberly-Clark Health Care
Address: 1400 Holcomb Bridge Road Roswell, GA 30076-2190, USA
Establishment Registration #: 1033422

Contact Name: Thomas Kozma, Director of Regulatory Affairs
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phone: (770) 587-8393
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Date: July 11, 2014

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification:	Class II per 21 CFR 880.6850
Classification Name:	Sterilization Wrap
Common/Usual Name:	Sterilization Wrap
Product Code:	FRG
Proprietary Name	KIMGUARD® ONE-STEP® Sterilization Wrap (Models: KC100, KC200, KC300, KC400, KC500, and KC600)

2. PREDICATE DEVICES

KIMGUARD* ONE-STEP* Sterilization Wrap, which is currently manufactured and distributed by Kimberly-Clark Corporation, (K082177 and K091685).

3. INDICATIONS FOR USE

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to enclose another medical device that is to be sterilized by a healthcare provider using:

- Gravity Steam at 250°F/121°C for 30 minutes.

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) allowed sterilization of the enclosed devices by the Gravity Steam Sterilization Systems (250°F/121°C for 30 minutes).

KIMGUARD* ONE-STEP* Sterilization Wrap Recommendations for Use within Gravity Steam Systems are provided in Table 1.

TABLE 1: Recommended Loads for KIMGUARD ONE-STEP* Sterilization Wrap for use with Gravity Steam* Sterilization Systems (250°F/121°C for 30 minutes)			
KIMGUARD* ONE-STEP* Sterilization Wrap Models	**Intended Loads[1]**	**Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study**	**Description of Loads Used in Sterility Maintenance Validation Study[2]**
KC100	Very Light Weight Package (for example batteries)	3 lbs.	1 tray liner 20" x 25" 12.5" x 9" x 1" Tray 1 lb of metal mass
KC200	Light Weight Package (for example telescope with light cord)	6 lbs.	1 tray liner 20" x 25" 10" x 20" x 3 ½ Tray 3 lbs of metal mass
KC300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	1 tray liner 20" x 25" 10" x 20" x 3 ½Tray 6 lbs of metal mass
KC400	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs.	1 tray liner 20" x 25" 10" x 20" x 3 ½ Tray 10 lbs of metal mass
KC500	Heavyweight Package (for example: general use medical instruments)	17 lbs.	1 tray liner 20" x 25" 11" x 22" x 3 ½Tray 12 lbs of metal mass
KC600	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs.	1 tray liner 20" x 25" 11" x 22" x 3 ½Tray 20 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 the 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.

4. Device Description

KIMGUARD* ONE-STEP* Sterilization Wrap is comprised of two sheets of KIMGUARD* Sterilization Wrap that is ultrasonically seamed on two edges. This seamed configuration allows for convenient wrapping of an article using two sheets simultaneously.

The sheets of sterilization wrap are square or rectangular fabric produced using a three-layer SMS (spunbound-meltblown-spunbound) process. The wrap fabric is composed of polypropylene with the addition of less than 2% by weight of phthalocyanine blue pigment, less than 1% by weight titanium dioxide pigment, and less than 0.008% by weight of anti-static treatment. The wrap allows a sterilized package to be opened aseptically.

5. Substantial Equivalence to Predicate Device

KIMGUARD ONE-STEP* Sterilization Wrap (i.e., subject of this Premarket Notification) is substantially equivalent to the predicate Kimberly-Clark KIMGUARD* ONE-STEP* Sterilization Wraps (K082177 and K091685) in technology, design, and materials.

Device Comparison Table (Technological, Design, & Materials)

Characteristics	Predicate Devices: KIMGUARD* ONE-STEP* Sterilization Wrap (K082177 and K091685)	Proposed Device: KIMGUARD* ONE-STEP* Sterilization Wrap
Manufacturer	Kimberly-Clark Corporation	Kimberly Clark Corporation
Regulation/Product Code	Sterilization Wrap: 880.6850 / FRG	Sterilization Wrap: 880.6850 / FRG **[SAME]**
Indications for Use	The device is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until opened. Not indicated for use for gravity steam sterilization.	KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to enclose another medical device that is to be sterilized by a healthcare provider using: • Gravity Steam at 250°F/121°C for 30 minutes. KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.
Sterilization Parameters	Pre-Vacuum Steam at 270°F/132°C for 4 minutes, EO with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes, and Amsco V-Pro ™ 1 and V-Pro 1 Plus Low Temperature Sterilization Systems	Gravity Steam at 250°F/121°C for 30 minutes.
Maintenance of Package Sterility	For models KC100, KC200, KC300, K400, KC500, and KC600 for up to 30 days.	Real-time testing following sterilization using Gravity Steam supports maintenance of package sterility for 30 days for all models of KIMGUARD* ONE-STEP* Sterilization Wrap.
Technology	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used. **[SAME]**
Device Design	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbound polypropylene layers (SMS)	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbound polypropylene layers (SMS) **[SAME]**
Method for bonding SMS layers	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern) **[SAME]**
Materials	Polypropylene with blue and white pigments	Polypropylene with blue and white pigments **[SAME]**
Distribution	Non-Sterile and Over-the-Counter	Non-Sterile and Over-the-Counter **[SAME]**
Single Use Device	Yes	Yes **[SAME]**

6. SUMMARY OF NONCLINICAL TESTS:

Performance of KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, KC600) has been tested as summarized below. All results of testing met the same acceptance criteria as the predicate devices demonstrating substantial equivalence to the predicate devices.

Summary of Testing Performed (Gravity Steam Sterilization)	Results
Sterilant Penetration	Passed
Package Integrity/Physical Properties	Passed
Drying and Aeration	Passed
Maintenance of Package Integrity	Passed
Biocompatibility (pre- and post-sterilization)	Passed

7. OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the KIMGUARD* ONE-STEP* Sterilization Wrap performs as intended as a sterilization packaging system of medical devices when terminally sterilized in Gravity Steam Sterilization Systems. These studies demonstrate that the KIMGUARD* ONE-STEP* Sterilization Wrap met the same criteria as the predicate devices and are substantially equivalent.

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

July 28, 2014

Kimberly-Clark Health Care
Dr. Thomas Kozma
Director of Regulatory Affairs
1400 Holcomb Bridge Road
Roswell, GA 30076-2190

Re: K141071
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: June 17, 2014
Received: June 18, 2014

Dear Dr. 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. 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 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. 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,

Mary S. Runner -S

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)*

K141071

Device Name

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

Indications for Use *(Describe)*

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to enclose another medical device that is to be sterilized by a healthcare provider using:

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
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