DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 10, 2014

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

Re: K140963
Trade/Device Name: KIMGUARD* Smart-Fold* Sterilization Wrap
(Models KC450 and KC650)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: September 25, 2014
Received: September 26, 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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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)* **K140963**

Device Name

KIMGUARD* Smart Fold* Sterilization Wrap (Models KC450 and KC650)

Indications for Use *(Describe)*

KIMGUARD* Smart Fold* Sterilization Wrap (KC450 and KC650) is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

- Advanced Sterilization Products' STERRAD® Sterilization Systems that include:
  - STERRAD® 100S
  - STERRAD® NX® [Standard Cycle, Advanced Cycle]
  - STERRAD® 100NX®). [Standard Cycle, Flex Cycle, EXPRESS cycle, DUO Cycle]

KIMGUARD* Smart Fold* Sterilization Wraps (KC450 and KC650) 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* Smart Fold* Sterilization Wrap (KC450 and KC650) allowed sterilization of the enclosed devices by the Advanced Sterilization Products STERRAD® Sterilization Systems (STERRAD® 100S, NX® [Standard Cycle and Advanced Cycle], and 100NX®. [Standard Cycle, Flex Cycle, EXPRESS cycle, DUO Cycle]). (Refer to the STERRAD® Sterilization System User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.)

The KC450 and KC650 models of the KIMGUARD* Smart Fold* Sterilization Wrap have been validated for use with the STERRAD® 100S, STERRAD® NX® , and STERRAD® 100 NX® cycles in Table 1.

KIMGUARD* Smart Fold* Sterilization Wrap Recommendations for Use with the Advanced Sterilization Products STERRAD® Sterilization Systems are provided in Table 2.

(continued on next 3 pages)

TABLE 1: Validated Advanced Sterilization Products (ASP) **STERRAD® 100S, STERRAD® NX®, and STERRAD® 100NX® Cycles**	
ASP STERRAD® System and Cycle	**Intended Load**
STERRAD® 100S	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.
STERRAD® NX® Advanced Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.
STERRAD® 100NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle.)
STERRAD® 100NX® Flex Cycle	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle).
STERRAD® 100NX® EXPRESS Cycle	Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaces such as the hinged portions of forceps and scissors, and rigid or semi-rigid endoscopes without lumens.
STERRAD® 100NX® DUO Cycle	One or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 2 mm or larger and a length of 250 mm or shorter. • Accessory devices that are normally connected to a flexible endoscope during use. • Flexible endoscopes without lumens

TABLE 2: Recommended Loads for KIMGUARD Smart-Fold* Sterilization Wrap for use with Advanced Sterilization Products (ASP) STERRAD® Sterilization Systems (STERRAD® 100S, NX® [Standard Cycle, Advanced Cycle], and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle])*

KIMGUARD* Smart Fold* Sterilization Wrap Models	Intended Loads[1]	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study	Description of Leads Used in Sterility Maintenance Validation Study
KC450	Moderate to heavy weight package (e.g., general use medical instruments	10.7 lbs.	•APTIMAX® Instrument Tray (23 in. x 11 in. x 4in.) with Tray Mat •Metal and non-metal instruments
KC650	Very heavy weight package (e.g., general use medical instruments	10.7 lbs.	•APTIMAX® Instrument Tray (23 in. x 11 in. x 4in.) with Tray Mat •Metal and non-metal instruments

[1]Intended loads include: Medical Instruments with and without lumens that include telescopes, endoscopes, cameras, light cords, and general use medical instruments

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)*

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

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This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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

Halyard Health (f/k/a Kimberly-Clark Health Care)
1400 Holcomb Bridge Road Roswell, GA 30076-2190, USA
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(920) 225-3408 (Fax)

DATE PREPARED:	November 07, 2014
TRADE NAME:	KIMGUARD* Smart-Fold* Sterilization Wrap (Models KC450 and KC650)
CLASSIFICATION NAME:	Sterilization Wrap
COMMON/USUAL NAME:	Sterilization Wrap
PRODUCT CODE:	FRG
DEVICE CLASSIFICATION:	Class II per 21 CFR §880.6850
PREDICATE DEVICES:	KimGuard* Smart-Fold* Sterilization Wrap (Models KC250, KC450, KC550, and KC650) cleared January 19, 2013 (K112300). KimGuard* ONE-STEP Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600 cleared August 20, 2013 (K113806)

INDICATIONS FOR USE

KIMGUARD* Smart Fold* Sterilization Wrap (KC450 and KC650) is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

- Advanced Sterilization Products' STERRAD® Sterilization Systems that include:
  - STERRAD® 100S
  - STERRAD® NX® [Standard Cycle, Advanced Cycle]
  - STERRAD® 100NX®). [Standard Cycle, Flex Cycle, EXPRESS cycle, DUO Cycle]

KIMGUARD* Smart Fold* Sterilization Wraps (KC450 and KC650) 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* Smart Fold* Sterilization Wrap (KC450 and KC650) allowed sterilization of the enclosed devices by the Advanced Sterilization Products STERRAD® Sterilization Systems (STERRAD® 100S, NX® [Standard Cycle and Advanced Cycle], and 100NX®. [Standard Cycle, Flex Cycle, EXPRESS cycle, DUO Cycle]). (Refer to the STERRAD®

Sterilization System User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.)

The KC450 and KC650 models of the KIMGUARD* Smart Fold* Sterilization Wrap have been validated for use with the STERRAD® 100S, STERRAD® NX® , and STERRAD® 100 NX® cycles in Table 1.

TABLE 1: Validated Advanced Sterilization Products (ASP) **STERRAD® 100S, STERRAD® NX®, and STERRAD® 100NX® Cycles**

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 100S	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.
STERRAD® NX® Advanced Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.
STERRAD® 100NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle.)
STERRAD® 100NX® Flex Cycle	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle).
STERRAD® 100NX® EXPRESS Cycle	Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaces such as the hinged portions of forceps and scissors, and rigid or semi-rigid endoscopes without lumens.
STERRAD® 100NX® DUO Cycle	One or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 2 mm or larger and a length of 250 mm or shorter. • Accessory devices that are normally connected to a flexible endoscope during use. • Flexible endoscopes without lumens

KIMGUARD* Smart Fold* Sterilization Wrap Recommendations for Use with the Advanced Sterilization Products STERRAD® Sterilization Systems are provided in Table 2.

TABLE 2: Recommended Loads for KIMGUARD Smart-Fold* Sterilization Wrap for use with Advanced Sterilization Products (ASP)* **STERRAD® Sterilization Systems (STERRAD® 100S, NX® [Standard Cycle, Advanced Cycle], and 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle])**

KIMGUARD* Smart Fold* Sterilization Wrap Models	**Intended Loads[1]**	**Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]**	**Description of Leads Used in Sterility Maintenance Validation Study**
KC450	Moderate to heavy weight package (e.g., general use medical instruments	10.7 lbs.	•APTIMAX® Instrument Tray (23 in. x 11 in. x 4in.) with Tray Mat •Metal and non-metal instruments
KC650	Very heavy weight package (e.g., general use medical instruments	10.7 lbs.	•APTIMAX® Instrument Tray (23 in. x 11 in. x 4in.) with Tray Mat •Metal and non-metal instruments

[1]Intended loads include: Medical Instruments with and without lumens that include telescopes, endoscopes, cameras, light cords, and general use medical instruments

[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 (i.e. the number and size of the fluid resistant linens or the weights of the metal mass)

DESCRIPTION OF DEVICE

KIMGUARD* Smart Fold* Sterilization Wrap is comprised of two pre-shaped sheets of KIMGUARD Sterilization Wrap (blue base sheet and white intermediate sheet), which include reinforcement strips, and adhesively seamed on three edges to allow convenient wrapping with two sheets (i.e., white and blue) simultaneously. The fabric is a nonwoven spunbond-meltblown-spunbond (SMS) composite sheet manufactured with polypropylene with 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 a potassium phosphate anti-static treatment. Two strips of blue SMS are adhesively bonded to the white SMS intermediate layer for added strength. These reinforcement strips also function as a “reference line” to indicate proper sterilization tray placement by the user. The Smart-Fold wrap also incorporates pull tabs comprised of blue SMS material for convenient aseptic opening of wrapped packages.

The following table compares the subject KIMGUARD* Smart Fold* Sterilization to the predicate KIMGUARD Sterilization Wrap devices.

General Comparison Matrix Overview: Subject and Predicate Device			
	Subject Device	**Predicate**	**Predicate**
Characteristic	**KIMGUARD* Smart-Fold* Sterilization Wrap (models KC450 and KC650)**	**KIMGUARD* Smart-Fold* Sterilization Wrap (models KC250, KC450, KC550, and KC650)**	**KIMGUARD* ONE-STEP* Sterilization Wrap (models KC100, KC200, KC300, KC400, KC500, KC600)**
510(k) Number	TBD	K112300	K113806
Regulation/ Product Code	Sterilization Wrap: 21CFR880.6850 FRG	**[SAME]**	**[SAME]**
Intended Use	Intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.	**[SAME]**	**[SAME]**
Sterilization Modality	STERRAD® (hydrogen peroxide) Sterilization Systems	Pre-Vacuum Steam and Ethylene Oxide	**[SAME]**
Base Materials of Construction	Three-layer SMS (spunbond-meltblown-spunbond) fabric	**[SAME]**	**[SAME]**
Packaging	Bulk and Non-sterile	**[SAME]**	**[SAME]**
Use	Over the Counter/Single Use	**[SAME]**	**[SAME]**

SUMMARY OF NONCLINICAL TESTS

Performance testing was conducted to show that the KIMGUARD* Smart Fold* Sterilization Wrap maintains sterility until used, after completion of the sterilization processes provided by the STERRAD® Sterilization Systems. The following Table summarizes performance evaluations performed.

Performance Requirement	Results
STERRAD Sterilant Penetration	Passed
Material Compatibility/Biocompatibility post-sterilization using maximum hydrogen peroxide concentration • Cytotoxicity per ISO 10993-5:2009 Elution Method using MEM extraction • Dermal Irritation per ISO 10993-10:2010, Intracutaneous reactivity using two extracts (i.e., 0.9% Sodium Chloride, USP and Sesame Oil, NF)	Passed
Material Usability post-sterilization	Passed
Maintenance of Package Integrity (180 Days)	Passed

OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the KIMGUARD* Smart Fold* Sterilization Wrap performs as intended as a sterilization packaging system of medical devices when sterilized in the STERRAD® Sterilization Systems. These studies show that the KIMGUARD* Smart Fold* Sterilization Wrap (KC450 and KC650) met the same criteria as the predicate device and are substantially equivalent.