October 10, 2019

Owens & Minor (O&M) Halyard, Inc
% Peter Kalkbrenner
Director of Engineering
Sterilucent, Inc
Minneapolis, Minnesota 55413

Re: K192147
Trade/Device Name: ONE-STEP Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: August 9, 2019
Received: August 13, 2019

Dear Peter Kalkbrenner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192147

Device Name
Halyard ONE-STEP* Sterilization Wrap

Indications for Use *(Describe)*
The Halyard ONE-STEP* Sterilization Wraps are intended to allow sterilization of the enclosed devices by the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (i.e., both the Lumen and Flexible Cycles). Additionally, the Halyard ONESTEP Sterilization Wrap was validated to allow effective aeration under the pre-programmed HC 80TT Sterilization Cycles. All models of the Halyard ONE-STEP Sterilization Wrap have been validated for use with the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer cycles as described below:

Lumen Cycle:
Reusable metal and nonmetal devices including devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors and up to fifteen (15) stainless steel lumens per load with the following dimensions:
Single or dual channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are:
$\geq$ 0.77 mm internal diameter (ID) and $\leq$ 410 mm long, or $\geq$ 1.33 mm ID and $\leq$ 430 mm long;
and, Triple channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are $\geq$ 1.00 mm ID and $\leq$ 310 mm long. (Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 20.1 lb. per load).

Flexible Cycle:
Reusable rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces such or mated surfaces such as the hinged portion of forceps or scissors;
Single channel flexible endoscopes with flexible lumens that are $\geq$ 1.00 mm ID and $\leq$ 1280 mm long; and Dual channel flexible endoscopes with flexible lumens that are $\geq$ 0.80 mm ID and $\leq$ 1000 mm long.
(Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 25 lb. per load).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K192147 **510K Summary**

Submitted by:	**O&M Halyard, Inc.**
Contact Person:	Steven Dowdley Associate Director of Regulatory Affairs O&M Halyard Inc. Steven.dowdley@hyh.com 678-451-8062
Date of Summary:	October 8, 2019
Device Trade Name:	Halyard ONE-STEP* Sterilization Wrap
Common or Usual Name:	Sterilization Wrap
Classification:	21 CFR 880.6850
Class:	Class II
Product Code:	FRG
Predicate Device(s):	Halyard ONE-STEP* Sterilization Wrap - K141712
Device Description:	Halyard ONE-STEP* Sterilization Wrap is comprised of two sheets of Halyard 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 phthalocyanine blue pigment, titanium dioxide pigment, and antistatic treatment. The wrap allows a sterilized package to be opened aseptically.
Indications for Use	The Halyard ONE-STEP Sterilization Wraps are intended to allow sterilization of the enclosed devices by the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (i.e., both the Lumen and Flexible Cycles). Additionally, the Halyard ONE-STEP Sterilization Wrap was validated to allow effective aeration under the pre-programmed HC 80TT Sterilization Cycles. All models of the Halyard ONE-STEP Sterilization Wrap have been validated for use with the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer cycles as described below: Lumen Cycle: Reusable metal and nonmetal devices including devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors and up to fifteen (15) stainless steel lumens per load with the following dimensions: Single or dual channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are: ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm long, or ≥ 1.33 mm ID and ≤ 430 mm long; and, Triple channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are ≥ 1.00 mm ID and ≤ 310 mm long. (Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 20.1 lb. per load). Flexible Cycle Reusable rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces such or mated surfaces such as the hinged portion of forceps or scissors, Single channel flexible endoscopes with flexible lumens that are ≥100 mm ID and ≤1280 mm long, and Dual channel flexible endoscopes with flexible lumens that are ≥0.80 mm ID and ≤1000 mm long (Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (ie: 25 lb per load)

Technological Characteristics Table:

	Proposed **Halyard ONE-STEP*** **Sterilization Wrap (K192147)**	**Predicate** **KIMGUARD ONE-STEP*** **Sterilization Wrap (K141712)**
Manufacturer	Halyard	Halyard
Device Model numbers	H100 H200 H300 H400 H500 H600	KC100 KC200 KC300 KC400 KC500 KC600 (Please note that the device model number are the same The alphabetical prefix on the product was changed when the company's name changed from Kimberly Clark to Halyard)
Common or Usual Name:	Sterilization Wrap	Sterilization Wrap
Classification:	21 CFR 880.6850	21 CFR 880.6850
Class:	II	II
Product Code	FRG	FRG
Manufacturer	Halyard	Halyard
Indication for Use	The Halyard ONE-STEP Sterilization Wraps are intended to allow sterilization of the enclosed devices by the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (ie. both the Lumen and Flexible Cycles) Additionally, the Halyard ONESTEP Sterilization Wrap was validated to allow effective aeration under the pre-programmed HC 80TT Sterilization Cycles. All models of the Halyard ONE-STEP Sterilization Wrap have been validated for use with the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer cycles as described below	KIMGUARD ONE-STEP* Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using Sterilucent PSD-85 Hydrogen Peroxide Sterilizer that include • Lumen Cycle and • Non-Lumen Cycle 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

	Lumen Cycle Reusable metal and nonmetal devices including devices with diffusion- restricted spaces such as the hinged portion of forceps and scissors and up to fifteen (15) stainless steel lumens per load with the following dimensions: Single or dual channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm long, or ≥ 1.33 mm ID and ≤ 430 mm long, and, Triple channeled rigid and semi- rigid endoscopes, with stainless steel lumens that are ≥ 1.00 mm ID and ≤ 310 mm long (Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (ie. 20.1 lb per load) Flexıble Cycle Reusable rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces such or mated surfaces such as the hinged portion of forceps or scissors, Single channel flexible endoscopes with flexible lumens that are ≥ 1.00 mm ID and ≤1280 mm long, and Dual channel flexible endoscopes with flexible lumens that are ≥ 0.80 mm ID and ≤1000 mm long (Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (ie. 25 lb per load)	ONE-STEP* Sterilization Wraps (KC100, KC200, KC300, KC400, KC500,and KC600) allowed sterilization of the enclosed devices by the Sterilucent PSD- 85 Hydrogen Peroxide Sterilizer (ie. both the Lumen and Non-Lumen Cycles) Additionally, the KIMGUARD ONE-STEP* Sterilization Wrap was validated to allow effective aeration under the pre- programmed PSD-85 Sterilization Cycles The PSD-85 Lumen Cycle has been validated to sterilize a load of up to ten (10) pounds (combined pouch and wrapped tray load) containing a maximum of ten (10) single channel stainless steel lumens per load with the following dimensions • An inside diameter of 1 mm or larger and a length of 60 mm or shorter, • An inside diameter of 2 mm or larger and a length of 250 mm or shorter, • An inside diameter of 3 mm or larger and a length of 350 mm or shorter The PSD-85 Non-Lumen Cycle has been validated to sterilize a load of up to 25 pounds (combined pouch and wrapped tray load) All models of the KIMGUARD ONE- STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, and KC600) have been validated for use with the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer cycles listed below Lumen Reusable metal and nonmetal devices including devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors and up to 10 single channel stainless steel lumened devices of the following dimensions per chamber load o An inside diameter of 1 mm or larger and a length of 60 mm or shorter o An inside diameter of 2 mm or larger and a length of 250 mm or shorter o An inside diameter of 3 mm or larger and a length of 350 mm or shorter

		(Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (ie. 10 lbs per load) Non-Lumen Non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (ie. 25 lbs per load))
Sterilization Parameters	Stenlucent HC 80TT Hydrogen Peroxide Sterilizer that includes • Lumen Cycle • Flexible Cycle	Sterilucent PSD-85 Hydrogen Peroxide Sterilizer that includes • Lumen Cycle • Non-Lumen Cycle
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)	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)
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)
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)
Materials	Polypropylene with blue and white pigments	Polypropylene with blue and white pigments
Distribution	Non-Sterile and Over-the-Counter	Non-Sterile and Over-the-Counter
Single Use Device	Yes	Yes

Performance Testing Summary

Performance Testing (Bench): Performance of Halyard ONE-STEP* Sterilization Wrap (H100, H200, H300, H400, H500, H600) has been evaluated to show that all results of testing met acceptance criteria, demonstrating that the Halyard ONE-STEP* Sterilization Wrap allows sterilization of contents by the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer and maintains sterility of contents for the designated test period (30 Days).

Test	Description	Result
Sterilant Penetration / Efficacy	Demonstration of no growth of challenge microorganisms in inoculation BI placement sites of claimed challenge loads after exposure to worst case half-cycles sterilization cycle conditions for both the lumen and flexible sterilization cycles.	Passed
Maintenance of Package Integrity	Demonstration of no growth of microorganisms after 30 Day event-related shelf life testing using simulated worst case handling conditions.	Passed
Simulated use testing	Demonstration no growth of challenge microorganisms, after sterilization, using an inoculum in the presence of a defined soil challenge	Passed

Performance Testing (Clinical): Clinical evaluations were not required and therefore are not submitted with this 510(k)

Discussion: The Halyard ONE-STEP* Sterilization Wrap and the predicate device are both intended to enclose another medical device that is to be sterilized by a healthcare provider, to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Both devices have the same intended use, design, materials, specifications, and composition, and are manufactured using the exact same production methods

Overall Performance Conclusions Based on the nonclinical tests performed the subject device, the Halyard ONE-STEP* Sterilization Wrap for use with the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer, is as safe, as effective and performs as well or better than the legally marketed predicate device, the Halyard ONE-STEP* Sterilization Wrap for use with the PSD-85 Hydrogen Peroxide Sterilizer