July 27, 2022

Owens & Minor (O&M) Halyard, Inc.
Anureet Singh
Regulatory Affairs Specialist II
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K214007
Trade/Device Name: HALYARD ONE-STEP Sterilization Wrap, HALYARD QUICK CHECK Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: June 29, 2022
Received: June 30, 2022

Dear Anureet Singh:

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 Clarence W. Murray, III, Ph.D.
Acting Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214007

Device Name
HALYARD* ONE-STEP* Sterilization Wrap and
HALYARD* QUICK CHECK* Sterilization Wrap

Indications for Use *(Describe)*
HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using the Stryker Sterizone VP4 Sterilizer Cycle 1.

The HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to allow sterilization of the enclosed devices by the Stryker Sterizone VP4 Sterilizer Cycle 1. All models of the Halyard ONE-STEP and QUICK CHECK Sterilization Wrap have been validated for use with the Stryker Sterizone VP4 Sterilizer Cycle 1 as described below:

Type of Device	HALYARD ONE-STEP* and QUICK CHECK* Validation Loads Description in the Stryker Sterizone VP4 Sterilizer Cycle 1	Validated Sterilization Wrap Grades[B]
General instruments	Load consisted of three (3) trays each containing three (3) lb of general medical instruments. The load included: • General devices representing the following geometries: Box-lock hinge Pivot hinge Luer-lock Testing was performed with trays wrapped in H100 sterilization wrap. **Load #7[A] –** Consisted of three (3) trays each containing 25 lb of general medical instruments, for a total of 75 lb per load (excluding the loading rack). The load included: • General devices representing the following geometries: Box-lock hinge Pivot hinge Luer-lock Testing was performed with trays wrapped in H600 sterilization wrap.	**H100[C]** **H200** **H300** **H400** **H500** **H600[C]**
Rigid channel instruments	**Load #4[A] -** Consisted of 15 lumens from rigid and semi-rigid channeled devices. The load included: • Three (3) double channel (six (6) lumens) semi-rigid endoscopes (ureteroscope - 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged in three (3) sterilization trays including appropriate silicone brackets. • Additional rigid channel instruments (nine (9) lumens) were added. Testing was performed with trays wrapped in H400 and H600 sterilization wrap.	**H400[C]** **H500** **H600[C]**
Single and double channel flexible endoscopes	**Load #8[A] -** Consisted of five (5) lumens from single and double channel flexible endoscopes. The load included: • Two (2) double channel flexible endoscopes (ureteroscope) with inside diameter of 1 mm and lengths of 850 mm and 989 mm; • One (1) single channel flexible endoscope (ureteroscope) with inside diameter of 1 mm and length of 850 mm; • The endoscopes were individually packaged in sterilization trays, including appropriate silicone brackets. Testing was performed with trays wrapped in H400 and H600 sterilization wrap.	**H400[C]** **H500** **H600[C]**
Multi-channel flexible endoscopes	**Load #9[A] -** Consisted of one (1) multichannel flexible endoscope with four (4) channels. The load included: • One (1) multi flexible endoscope (colonoscope) with no more than four (4) channels having inside diameter of 1.2 mm and lengths of 1955 mm or inside diameter of 1.45 mm and lengths of 3500 mm, packaged individually in a sterilization tray. Testing was performed with trays wrapped in H400 and H600 sterilization wrap.	**H400[C]** **H500** **H600[C]**

A: Representative Sterizone® VP4 Sterilizer Cycle 1 Validation Load from K172191. B: HALYARD* ONE-STEP* and QUICK CHECK* Sterilization Wrap are comprised of two sheets of Halyard Sequential Sterilization Wrap ultrasonically bonded together on two sides. Therefore, these grades are applicable to HALYARD* ONE-STEP*, QUICK CHECK* and Sequential Sterilization Wrap. C: Indicates the bracketed grades for validation testing.

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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510(k) Summary – K214007

Submitter:	O&M Halyard, Inc. 9120 Lockwood Boulevard Mechanicsville, VA 23116 Phone: 804-723-7000/800-488-8850 Fax: 804-723-7100
Regulatory Contact:	Anureet Singh Regulatory Affairs Specialist II O&M Halyard, Inc. 1 Edison Drive Alpharetta, GA 30005
Date of Summary:	25 July 2022
Device Trade Name:	HALYARD* ONE-STEP* Sterilization Wrap and HALYARD* QUICK CHECK* Sterilization Wrap
Common Name:	Sterilization Wrap
Classification Name:	Sterilization wrap (21 CFR 880.6850, Product Code FRG)
Predicate Device:	Halyard ONE-STEP Sterilization Wrap, K192147
Device Description:	Halyard Sterilization Wrap is supplied to the customer as bulk packages of single sheets, where in accordance with standard hospital practices, two sheets are then used to wrap a medical device or a collection of medical devices for sterilization. HALYARD ONE-STEP and HALYARD QUICK CHECK Sterilization Wraps are comprised of two sheets of HALYARD* Sequential Sterilization Wrap ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously. Sterilization wrap is a square or rectangular sheet made of three-layer SMS (spunbond-meltblown-spunbond) polypropylene fabric treated with an antistatic treatment. The wrap allows a sterilized package to be opened aseptically. The HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using the Stryker Sterizone VP4 Sterilizer Cycle 1 which is a dual-sterilant, low temperature sterilizer that uses vaporized hydrogen peroxide (H_2O_2) and ozone (O_3) in a single cycle. All models of the Halyard ONE-STEP and QUICK CHECK Sterilization Wrap have been validated for use with the Stryker Sterizone VP4 Sterilizer Cycle 1 as described below.
Indication for Use:	HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using the single cycle Stryker Sterizone VP4 Sterilizer Cycle 1. The HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to allow sterilization of the enclosed devices by the Stryker Sterizone

VP4 Sterilizer Cycle 1. All models of the Halyard ONE-STEP and QUICK CHECK Sterilization Wrap have been validated for use with the Stryker Sterizone VP4 Sterilizer Cycle 1 as described below:

Type of Device	HALYARD ONE-STEP* and QUICK CHECK* Validation Loads Description in the Stryker Sterizone VP4 Sterilizer Cycle 1	Validated Sterilization Wrap Grades[B]
General instruments	Load consisted of three (3) trays each containing three (3) lb of general medical instruments. The load included: • General devices representing the following geometries: Box-lock hinge Pivot hinge Luer-lock Testing was performed with trays wrapped in H100 sterilization wrap.	**H100[C]** **H200** **H300** **H400** **H500** **H600[C]**
	Load #7[A] – Consisted of three (3) trays each containing 25 lb of general medical instruments, for a total of 75 lb per load (excluding the loading rack). The load included: • General devices representing the following geometries: Box-lock hinge Pivot hinge Luer-lock Testing was performed with trays wrapped in H600 sterilization wrap.	
Rigid channel instruments	**Load #4[A] -** Consisted of 15 lumens from rigid and semi-rigid channeled devices. The load included: • Three (3) double channel (six (6) lumens) semi-rigid endoscopes (ureteroscope - 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged in three (3) sterilization trays including appropriate silicone brackets. • Additional rigid channel instruments (nine (9) lumens) were added. Testing was performed with trays wrapped in H400 and H600 sterilization wrap.	**H400[C]** **H500** **H600[C]**
Single and double channel flexible endoscopes	**Load #8[A] -** Consisted of five (5) lumens from single and double channel flexible endoscopes. The load included: • Two (2) double channel flexible endoscopes (ureteroscope) with inside diameter of 1 mm and lengths of 850 mm and 989 mm; • One (1) single channel flexible endoscope (ureteroscope) with inside diameter of 1 mm and length of 850 mm; • The endoscopes were individually packaged in sterilization trays, including appropriate silicone brackets. Testing was performed with trays wrapped in H400 and H600 sterilization wrap.	**H400[C]** **H500** **H600[C]**
Multi-channel flexible endoscopes	**Load #9[A] -** Consisted of one (1) multichannel flexible endoscope with four (4) channels. The load included: • One (1) multi flexible endoscope (colonoscope) with no more than four (4) channels having inside diameter of 1.2 mm and lengths of 1955 mm or inside diameter of 1.45 mm and lengths of 3500 mm, packaged individually in a sterilization tray. Testing was performed with trays wrapped in H400 and H600 sterilization wrap.	**H400[C]** **H500** **H600[C]**

A: Representative Sterizone® VP4 Sterilizer Cycle 1 Validation Load from K172191. B: HALYARD* ONE-STEP* and QUICK CHECK* Sterilization Wrap are comprised of two sheets of Halyard Sequential Sterilization Wrap ultrasonically bonded together on two sides. Therefore, these grades are applicable to HALYARD* ONE-STEP*, QUICK CHECK* and Sequential Sterilization Wrap. C: Indicates the bracketed grades for validation testing.

Technological Characteristics Comparison Table:

	Proposed **HALYARD ONE-STEP and QUICK CHECK Sterilization Wrap (K214007)**	**Predicate** **HALYARD ONE-STEP Sterilization Wrap (K192147)**	**Same Similar, or Different**
Manufacturer	O&M Halyard, Inc.	O&M Halyard, Inc.	Same
Device Model Numbers	H100 H200 H300 H400 H500 H600	H100 H200 H300 H400 H500 H600	Same
Common or Usual Name	Sterilization Wrap	Sterilization Wrap	Same
Classification	21 CFR 880.6850	21 CFR 880.6850	Same
Class	II	II	Same
Product Code	FRG	FRG	Same
Indication for Use	HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using the Stryker Sterizone VP4 Sterilizer Cycle 1. The HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to allow sterilization of the enclosed devices by the Stryker Sterizone VP4 Sterilizer Cycle 1. All models of the Halyard ONE-STEP and QUICK CHECK Sterilization Wrap have been validated for use with the Stryker Sterizone VP4 Sterilizer Cycle 1 as described below: Type of Device: General instruments HALYARD ONE-STEP* and QUICK CHECK* Validation Loads Description in the Stryker Sterizone VP4 Sterilizer Cycle 1: Load consisted of three (3) trays each containing three (3) lb of general medical instruments. The load included general devices representing the following geometries: Box-lock hinge, Pivot hinge, Luer-lock. Testing was performed with trays wrapped in H100 sterilization wrap. Load #7[A] – Consisted of three (3) trays each containing 25 lb of general medical instruments, for a total of 75 lb per load (excluding the loading rack). The load included general devices representing the following geometries: Box-lock hinge, Pivot hinge, Luer-lock. Testing was performed with trays wrapped in H600 sterilization wrap.	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 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	Different

	Validated Sterilization Wrap Grades[B]: H100[C], H200, H300, H400, H500, H600[C] Type of Device: Rigid channel instruments HALYARD ONE-STEP* and QUICK CHECK* Validation Loads Description in the Stryker Sterizone VP4 Sterilizer Cycle 1: Load #4[A] - Consisted of 15 lumens from rigid and semi-rigid channeled devices. The load included: Three (3) double channel (six (6) lumens) semi-rigid endoscopes (ureteroscope - 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged in three (3) sterilization trays including appropriate silicone brackets. Additional rigid channel instruments (nine (9) lumens) were added. Testing was performed with trays wrapped in H400 and H600 sterilization wrap. Validated Sterilization Wrap Grades[B]: H400[C], H500, H600[C] Type of Device: Single and double channel flexible endoscopes HALYARD ONE-STEP* and QUICK CHECK* Validation Loads Description in the Stryker Sterizone VP4 Sterilizer Cycle 1: Load #8[A] - Consisted of five (5) lumens from single and double channel flexible endoscopes. The load included: Two (2) double channel flexible endoscopes (ureteroscope) with inside diameter of 1 mm and lengths of 850 mm and 989 mm; One (1) single channel flexible endoscope (ureteroscope) with inside diameter of 1 mm and length of 850 mm; The endoscopes were individually packaged in sterilization trays, including appropriate silicone brackets. Testing was performed with trays wrapped in H400 and H600 sterilization wrap. Validated Sterilization Wrap Grades[B]: H400[C], H500, H600[C] Type of Device: Multi-channel flexible endoscopes HALYARD ONE-STEP* and QUICK CHECK* Validation Loads Description in the Stryker Sterizone VP4 Sterilizer Cycle 1: Load #9[A] - Consisted of one (1) multichannel flexible endoscope with four (4) channels. The load included: One (1) multi flexible endoscope (colonoscope) with no more than four (4) channels having inside diameter of 1.2 mm and lengths of 1955 mm or inside diameter of 1.45 mm	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 (i.e. 25 lb per load).	

	and lengths of 3500 mm, packaged individually in a sterilization tray. Testing was performed with trays wrapped in H400 and H600 sterilization wrap. Validated Sterilization Wrap Grades[B]: H400[C], H500, H600[C] A: Representative Sterizone® VP4 Sterilizer Cycle 1 Validation Load from K172191. B: HALYARD* ONE-STEP* and QUICK CHECK* Sterilization Wrap are comprised of two sheets of Halyard Sequential Sterilization Wrap ultrasonically bonded together on two sides. Therefore, these grades are applicable to HALYARD* ONE-STEP*, QUICK CHECK* and Sequential Sterilization Wrap. C: Indicates the bracketed grades for validation testing.		
Sterilization Parameters	Stryker Sterizone VP4 Sterilizer Cycle 1 which is a dual-sterilant, low temperature sterilizer that uses vaporized hydrogen peroxide (H_2O_2) and ozone (O_3) in a single cycle	Sterilucent PSD-85 Hydrogen Peroxide Sterilizer that includes • Lumen Cycle • Flexible Cycle	Different
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 spunbond 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 spunbond 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

Summary of Performance Testing

Performance Testing (Bench): Performance testing of HALYARD ONE-STEP and QUICK CHECK Sterilization Wrap was evaluated and the results showed that acceptance criteria were met demonstrating that the HALYARD ONE-STEP and QUICK CHECK Sterilization Wrap allows sterilization of its contents using the Stryker Sterizone VP4 Sterilizer Cycle 1 and that sterility is maintained for the testing period of 12 months.

Summary of Non-Clinical Testing Performed

Purpose	Test	Acceptance Criteria	Results
Sterilant Penetration/Efficacy	ANSI/AAMI ST79 ANSI/AAMI/ISO 11138-7	Achieving a 10^{-6} sterility assurance level following processing in a worst-case half-cycle	Passed
Performance Testing (Non-sterile and Sterile)	ANSI/AAMI/ISO 11607-1 Annex B ISO 13938-2 ASTM D4966-12 CPSC 1610	Complies with the selected physical properties	Passed
Maintenance of Package Integrity	ANSI/AAMI/ISO 11607-1 ANSI/AAMI ST79	Maintain sterility for up to 12 months	Passed
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-7	Non-cytotoxic Non-irritating $H_2O_2 \leq 0.56$ µg/cm^2	Passed

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

Discussion: The HALYARD ONE-STEP and QUICK CHECK Sterilization Wrap in this submission and the predicate device submission are 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). The ONE-STEP and QUICK CHECK Sterilization Wrap in this submission and the predicate device submission have identical intended use, design, materials, specifications, and composition, and are manufactured using identical production methods. The different technological characteristics, that is, the Indication for Use and the Sterilization Parameters, do not affect the safety and effectiveness of the device as evidenced by the results of the nonclinical testing.

Overall Performance Conclusions: The conclusions drawn from the nonclinical tests demonstrate that the HALYARD ONE-STEP and QUICK CHECK Sterilization Wrap (K214007) is as safe, as effective, and performs as well as or better than the legally marketed HALYARD ONE-STEP Sterilization Wrap (K192147).