August 7, 2024

O&M Halyard, Inc.
Anureet Singh
Regulatory Affairs Manager
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K240330
Trade/Device Name: HALYARD* SMART-FOLD* Sterilization Wrap (H450);
HALYARD* SMART-FOLD* Sterilization Wrap (H650)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: February 2, 2024
Received: February 5, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.08.07 16:07:04 -04'00'

for: Christopher Dugard
Assistant Director
DHT4C: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240330

Device Name
HALYARD* SMART-FOLD* Sterilization Wrap (H450);
HALYARD* SMART-FOLD* Sterilization Wrap (H650)

Indications for Use *(Describe)*
HALYARD SMART-FOLD Sterilization Wrap (H450 and H650) is intended to enclose another medical device that is to be sterilized by a healthcare provider using the Advanced Sterilization Products STERRAD 100NX Sterilizer ULTRA GI Cycle.

The H450 and H650 models of the HALYARD SMART-FOLD Sterilization Wrap have been validated for use with the STERRAD 100NX ULTRA GI Cycle as follows:
• Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions of ≥1mm inner diameter x ≤1500mm in length, or ≥2mm inner diameter x ≤1630mm in length.
• One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle
Note 1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf.
Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD Sterilizer Cycle Selection table for ULTRA GI Cycle compatible duodenoscopes

The HALYARD SMART-FOLD Sterilization Wrap (H450, H650) is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.

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.

510(k) Summary K240330

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 Manager

Date of Summary: 05 August 2024

Device Trade Name: HALYARD® SMART-FOLD® Sterilization Wrap (H450);
HALYARD® SMART-FOLD® Sterilization Wrap (H650)

Common Name: Sterilization Wrap

Classification Name: Sterilization wrap (21 CFR 880.6850, Product Code FRG)

Predicate Device: K181959 (SMART-FOLD Sterilization Wrap)
Reference Device: K140963 (SMART-FOLD Sterilization Wrap)

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 SMART-FOLD Sterilization Wraps are comprised of two sheets of HALYARD® Sequential Sterilization Wrap. This allows for convenient wrapping with two sheets simultaneously.

The HALYARD SMART-FOLD Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using the Advanced Sterilization Products, Inc. (ASP) STERRAD 100NX Sterilizer ULTRA™ GI Cycle.

Indications for Use:

HALYARD SMART-FOLD Sterilization Wrap (H450 and H650) is intended to enclose another medical device that is to be sterilized by a healthcare provider using the Advanced Sterilization Products STERRAD 100NX Sterilizer ULTRA GI Cycle.

The H450 and H650 models of the HALYARD SMART-FOLD Sterilization Wrap have been validated for use with the STERRAD 100NX ULTRA GI Cycle as follows:

• Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions of ≥1mm inner diameter x ≤1500mm in length, or ≥2mm inner diameter x ≤1630mm in length.

• One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle

Note 1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf.

Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD Sterilizer Cycle Selection table for ULTRA GI Cycle compatible duodenoscopes

The HALYARD SMART-FOLD Sterilization Wrap (H450, H650) is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.

Technological Characteristics Comparison Table:

	Proposed **HALYARD SMART-FOLD Sterilization Wrap**	**Predicate** **HALYARD SMART-FOLD Sterilization Wrap (K181959)**	**Reference** **KIMGUARD Smart-Fold Sterilization Wrap (K140963)**	**Comparison**
Manufacturer	O&M Halyard, Inc.	Halyard Health, Inc.	Kimberly-Clark Health Care	Different
Device Model Numbers	H450 H650	H450 H650	KC450 KC650	Same
Common or Usual Name	Sterilization Wrap	Sterilization Wrap	Sterilization Wrap	Same
Classification	21 CFR 880.6850	21 CFR 880.6850	21 CFR 880.6850	Same
Class	II	II	II	Same
Product Code	FRG	FRG	FRG	Same
Intended Use	Intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.	Intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.	Intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.	Same
Indications for Use	HALYARD SMART-FOLD Sterilization Wrap (H450 and H650) is intended to enclose another medical device that is to be sterilized by a healthcare provider using the Advanced Sterilization Products STERRAD 100NX Sterilizer ULTRA GI Cycle. The H450 and H650 models of the HALYARD SMART-FOLD Sterilization Wrap have been validated for use with the STERRAD 100NX ULTRA GI Cycle as follows: • Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions of ≥1mm inner diameter x ≤1500mm in	HALYARD SMART-FOLD* Sterilization Wrap (H450, H650) is intended to enclose another medical device that is to be sterilized by a healthcare provider using Steris V-PRO Low Temperature Sterilization system that includes: • V-PRO 1 (Lumen Cycle) • V- PRO 1 Plus (Lumen and Non-Lumen Cycle) • V-PRO maX, V-PRO maX 2 and V-PRO 60 (Lumen, Non-Lumen, and Flexible Cycle) The HALYARD SMART-FOLD* Sterilization Wrap (H450, H650) is intended to allow sterilization of the enclosed medical device(s) and	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: o STERRAD 100S o STERRAD NX [Standard Cycle, Advanced Cycle] o 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	Different, includes additional indications for Use for ULTRA GI cycle.

	length, or ≥2mm inner diameter x ≤1630mm in length. • One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle Note 1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf. Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD Sterilizer Cycle Selection table for ULTRA GI Cycle compatible duodenoscopes The HALYARD SMART-FOLD Sterilization Wrap (H450, H650) is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.	to maintain sterility of the enclosed device(s) until used.	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.)	
Device Design	Two pre-shaped sheets of Halyard Sterilization Wrap, which include reinforcement zones, medical device placement reference line, a white inner layer, side-tabs with closure strips and pull-tabs to allow convenient wrapping with two sheets simultaneously	Two pre-shaped sheets of Halyard Sterilization Wrap, which include reinforcement zones, medical device placement reference line, a white inner layer, side-tabs with closure strips and pull-tabs to allow convenient wrapping with two sheets simultaneously	Two pre-shaped sheets of Halyard Sterilization Wrap, which include reinforcement zones, medical device placement reference line, a white inner layer, side-tabs with closure strips and pull-tabs to allow convenient wrapping with two sheets simultaneously	Same
Sterilant	Hydrogen Peroxide	Hydrogen Peroxide	Hydrogen Peroxide	Same
Technology	Polypropylene SMS material that allows sterilant to penetrate and maintain sterile barrier	Polypropylene SMS material that allows sterilant to penetrate and maintain sterile barrier	Polypropylene SMS material that allows sterilant to penetrate and maintain sterile barrier	Same
Materials	Each sheet is composed of a three-layer SMS (spunbond-meltblown-spunbond) polypropylene fabric treated with an antistatic treatment.	Each sheet is composed of a three-layer SMS (spunbond-meltblown-spunbond) polypropylene fabric treated with an antistatic treatment.	Each sheet is composed of a three-layer SMS (spunbond-meltblown-spunbond) polypropylene fabric treated with an antistatic treatment.	Same
Distribution	Non-Sterile Over-the-Counter	Non-Sterile Over-the-Counter	Non-Sterile Over-the-Counter	Same
Single Use Device	Yes	Yes	Yes	Same

Summary of Non-Clinical Performance Testing:
Performance testing of HALYARD SMART-FOLD Sterilization Wrap was evaluated and the results showed that acceptance criteria were met demonstrating that the HALYARD SMART-FOLD Sterilization Wrap allows sterilization of its contents using the STERRAD 100NX Sterilizer ULTRA GI Cycle and that sterility is maintained for the testing period of 90 days.

Summary of Non-Clinical Testing Performed

Purpose	Test	Acceptance Criteria	Result
Sterilant Penetration/Efficacy	ISO 14937 AAMI TIR No 12-2010	Achieving a 10^{-6} sterility assurance level following processing in a worst-case half-cycle	Pass
Performance Testing (Pre-Sterilization and Post-Sterilization)	ANSI/AAMI/ISO 11607-1 Annex B ISO 13938-2 ASTM D4966-12 CPSC 1610	Complies with the selected physical properties	Pass
Maintenance of Package Integrity	ANSI/AAMI/ISO 11607-1 ANSI/AAMI ST79 AAMI TIR No 12-2010 ANSI/AAMI/ISO 14937	Maintain sterility for up to 90 days	Pass
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12 ISO 14937	Non-cytotoxic Non-irritating Residual level $\leq$ 9100 $\mu g/cm^2$	Pass

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

Discussion:
The HALYARD SMART-FOLD 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 SMART-FOLD 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 Indications for Use, do not affect the safety and effectiveness of the device as evidenced by the results of the nonclinical testing.

Conclusion:
The conclusions drawn from the non-clinical tests demonstrate that the HALYARD SMART-FOLD Sterilization Wrap (K240330) is as safe, as effective, and performs as well as or better than the legally marketed device, the HALYARD SMART-FOLD Sterilization Wrap (K181959).