March 22, 2019

Owens & Minor Halyard, Inc
Angela L. Bunn, RAC
Director, Regulatory Affairs, Products Division
5405 Windward Parkway
Alpharetta, GA 30004

Re: K181959
Trade/Device Name: HALYARD SMART-FOLD* Sterilization Wrap (Models: H450, H650)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: February 19, 2019
Received: February 21, 2019

Dear Angela L. Bunn:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181959

Device Name
HALYARD SMART-FOLD* Sterilization Wrap (Models: H450, H650)

Indications for Use *(Describe)*

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. The wrap was validated in the following pre-programmed cycles:

- STERIS V-PRO 1 low temperature sterilization system (lumen cycle),
- STERIS V-PRO 1 Plus low temperature sterilization system (Lumen and Non-lumen cycle),
- STERIS V-PRO maX low temperature sterilization system (Lumen, Non-Lumen cycle, flexible cycle),
- STERIS V-PRO 60 sterilizer (Lumen, Non-Lumen cycle, flexible cycle)
- STERIS V-PRO maX 2 low temperature sterilization system (Lumen, Non-Lumen cycle, flexible cycle)

HALYARD SMART-FOLD* Sterilization Wrap (H450, H650) is intended to allow terminal sterilization of medical devices using vaporized hydrogen peroxide (VHP) and to maintain sterility of the enclosed device(s) until used within the period of time for which performance data demonstrating maintenance of sterility has been provided.

Table 1 Summary of V-PRO Low Temperature Sterilizer System Cycles

Sterilization Cycle	Sterilizer Model				
	V-PRO 1	V-PRO 1 Plus	V-PRO maX	V-PRO 60	V-PRO maX 2
Lumen	Yes	Yes	Yes	Yes	Yes
Non-Lumen	N/A	Yes	Yes	Yes	Yes
Flexible	N/A	N/A	Yes	Yes	Yes

Test results validated that HALYARD SMART-FOLD* Sterilization Wrap (H450, H650) allowed sterilization of the enclosed devices using Steris V-PRO Low Temperature Sterilization system.All models of the HALYARD SMART-FOLD* Sterilization Wrap (H450, H650) have been validated for use with the STERIS V-PRO Low Temperature Sterilization System cycles (Table 2, Table 3, and Table 4).

TABLE 2: Validated Low Temperature Sterilization Products STERIS V-PRO 1, STERIS V-PRO 1 Plus, STERIS V-PRO maX, STERIS V-PRO maX 2, and STERIS V-PRO 60, Lumen[1] Cycles.

Note: Refer to the Manufacturer's User's Guide for complete instructions on load and cycle for each STERIS V-PRO System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS – VPRO

STERIS V-PRO System Lumen Cycle	Intended Load
STERIS V-PRO 1 **STERIS V-PRO 1 Plus** **STERIS V-PRO maX** **STERIS V-PRO maX 2**	**STERIS V-PRO maX,** Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: - Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤500mm in length - Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length - Triple channeled devices with stainless steel lumens that are • ≥ 1.2 mm ID and ≤ 275 mm in length • ≥1.8 mm ID and ≤ 310 mm in length • or • ≥ 2.8 mm ID and ≤ 317 mm in length **STERIS V-PRO maX 2** • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: - Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤500mm in length - Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length - Triple channeled devices with stainless steel lumens that are • ≥ 1.2 mm ID and ≤ 275 mm in length • ≥1.8 mm ID and ≤ 310 mm in length or • ≥ 2.8 mm ID and ≤ 317 mm in length **STERIS V-PRO 1 STERIS V-PRO 1 Plus** The V-PRO 1 Cycle and the V-PRO 1 Plus Lumen Cycle can sterilize* instruments/devices with the following features: • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. • Medical devices with a single lumen with: - an inside diameter of 3 mm or larger and a length of 400 mm or shorter - an inside diameter of 2 mm or larger and a length of 250 mm or shorter - an inside diameter of 1 mm or larger and a length of 125 mm or shorter
STERIS V-PRO 60	The V-PRO 60 sterilizer's Lumen cycle can sterilize: • Instruments with diffusion- restricted spaces such as the hinged portion of forceps and scissors. • Non- Lumened devices including non- lumened rigid and semi-rigid endoscopes • Medical Devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ϒ Single or dual lumen devices with stainless steel lumens that are o ≥ 0.77 mm (~ 1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length ϒ Triple lumen devices with stainless steel lumens that are o ≥ 1.2 mm (~ 3/64") ID and ≤ 275 mm (~ 10 – 55/64") in length o ≥ 1.8 mm (~ 5/64") ID and ≤ 310 mm (~ 12 – 13/64") in length o or o ≥ 2.8 mm (~ 7/64") ID and ≤ 317 mm (~ 12 – 31/64") in length

1The Non-Lumen articles can be processed in the Lumen cycle as it takes mixed loads

TABLE 3: Validated Low Temperature Sterilization Products STERIS V-PRO 1 Plus, STERIS V-PRO maX, STERIS V-PRO maX 2, andSTERIS V-PRO 60, Non-Lumen **Cycles** **Note: Refer to the User's Guide for complete instructions on load and cycle for each STERIS V-PRO System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS – VPRO**	
STERIS V-PRO System Non-Lumen Cycle	**Intended Load**
STERIS V-PRO 1 Plus **STERIS V-PRO maX** **STERIS V-PRO maX 2**	**STERIS V-PRO maX 2** Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes. **STERIS V-PRO maX** The Non-Lumen Cycle can sterilize instruments/devices with the following features: • Non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors. **STERIS V-PRO 1 Plus** The V-PRO 1 Plus Non-Lumen Cycle can sterilize instruments/devices with the following features: Non-Lumen instruments including non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.
STERIS V-PRO 60	The V-PRO 60 Non-Lumen Cycle can sterilize instruments/devices with the following features: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

TABLE 4: Validated Low Temperature Sterilization Products STERIS V-PRO maX. STERIS V-PRO maX 2, and STERIS V-PRO 60, Flexible Cycles **Note: Refer to the User's Guide for complete instructions on load and cycle for each STERIS V-PRO System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS – VPRO**	
STERIS V-PRO System Flexible Cycle	**Intended Load**
STERIS V-PRO maX **STERIS V-PRO maX 2**	**STERIS V-PRO maX 2** **The Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) or bronchoscopes in either of two load configurations:** **1. Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load. The flexible endoscopes may contain either:** • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 998 mm in length And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length **2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. The flexible endoscopes may contain either:** • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length **STERIS V-PRO maX** The Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) or bronchoscopes in either of two load configurations: 1. Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load[3]. The flexible endoscopes my contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 998 mm in length - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length 2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors[4]. The flexible endoscopes my contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 998 mm in length - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
STERIS V-PRO 60	The V-PRO 60 sterilizer's 60 flexible cycle can sterilize: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: • Single or dual lumen device with lumens that are > 1 mm (~3/64") ID and <990 mm (38-63/34") in length

HALYARD SMART-FOLD* Sterilization Wraps (H450, H650) Recommendations for Use with STERIS V-PRO Low Temperature Sterilization System is provided in (Table 5).

TABLE 5: Halyard Smart-Fold* Sterilization Wrap Recommendations[2] for Use with Steris V-PRO Sterilizer

SMART-FOLD* Sterilization Wrap Model	Intended Loads[3]	Maximum Wrapped Package Content Weights [4]						
		STERIS V-PRO® 1, V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Lumen	STERIS V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Non-Lumen	STERIS V-PRO® maX V-PRO® maX 2 Flexible	STERIS V-PRO® 60 Lumen	STERIS V-PRO® 60 Non-Lumen	STERIS V-PRO® 60 Flexible	STERIS V-PRO® maX 2 Fast Non-Lumen[5]
H450	Moderate to Heavyweight Package (for example: general use medical instruments)	13 lbs	13 lbs.	13 lbs.	11 lbs.	12 lbs.	The validation studies were conducted with one flexible endoscope packaged into a tray with silicone wrap, and instrument organizers and light cord (if not integral to scope) and no additional load.	N/A
H650	Moderate to Heavyweight Package (for example: general use medical instruments)	19.65 lbs.	25 lbs.- max2, 19.65 – max, 1 and 1 plus	24 lbs.	11 lbs.	12 lbs.	The validation studies were conducted with one flexible endoscope packaged into a tray with silicone wrap, and instrument organizers and light cord (if not integral to scope) and no additional load.	N/A

[2]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 most appropriate for each intended use.

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

[4]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 for HALYARD SMART-FOLD Sterilization Wraps.

[5]The Fast-Non-Lumen cycle is intended to sterilize pouched instruments trays only and is therefore not intended to be used for sterilization of HALYARD SMART-FOLD* Sterilization wraps.

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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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY
HALYARD SMART-FOLD* Sterilization Wrap (H450, H650)

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

Owens & Minor Halyard, Inc
5405 Windward Parkway
Alpharetta, GA 30004

Contact Name: Angela L. Bunn, RAC
Director, Regulatory Affairs
Products Division
Tel: 470.448.5856
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510(k) Number: K181959

Establishment Registration Number: 3014421917

Date: March 22, 2019

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: HALYARD SMART-FOLD* Sterilization Wrap (Models: H450, H650)

PREDICATE DEVICE:

K142782- KIMGUARD ONE-STEP* Sterilization Wrap
(Models: H100, H200, H300, H400, H500, H600)

REFERENCE DEVICE:

K140963 – KIMGUARD* SMART-FOLD* sterilization wrap
(Models: KC450, KC650)

INDICATIONS FOR USE

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. The wrap was validated in the following pre-programmed cycles:

- STERIS V-PRO 1 low temperature sterilization system (lumen cycle),
- STERIS V-PRO 1 Plus low temperature sterilization system (Lumen and Non-lumen cycle),
- STERIS V-PRO maX low temperature sterilization system (Lumen, Non-Lumen cycle, flexible cycle),
- STERIS V-PRO 60 low temperature sterilization system (Lumen, Non-Lumen cycle, flexible cycle)
- STERIS V-PRO maX 2 low temperature sterilization system (Lumen, Non-Lumen cycle, flexible cycle)

HALYARD SMART-FOLD* Sterilization Wrap (H450, H650) is intended to allow terminal sterilization of medical devices using vaporized hydrogen peroxide (VHP) and to maintain sterility of the enclosed device(s) until used within the period of time for which performance data demonstrating maintenance of sterility has been provided.

Table 1 Summary of V-PRO Low Temperature Sterilizer System Cycles

Sterilization Cycle	Sterilizer Model				
	V-PRO 1	**V-PRO 1 Plus**	**V-PRO maX**	**V-PRO 60**	**V-PRO maX 2**
Lumen	Yes	Yes	Yes	Yes	Yes
Non-Lumen	N/A	Yes	Yes	Yes	Yes
Flexible	N/A	N/A	Yes	Yes	Yes

Test results validated that HALYARD SMART-FOLD* Sterilization Wrap (H450, H650) allowed sterilization of the enclosed devices using Steris V-PRO Low Temperature Sterilization system. All models of the HALYARD Smart Fold Sterilization Wrap (H450, H650) have been validated for use with the Steris V-PRO Low Temperature Sterilization System cycles (Table 1.2, Table 1.3, and Table 1.4).

***TABLE 2: Validated Low Temperature Sterilization Products STERIS V-PRO 1, STERIS V-PRO 1 Plus, STERIS V-PRO maX, STERIS V-PRO maX 2, and STERIS V-PRO 60, Lumen[1]* Cycles.**

Note: Refer to the Manufacturer's User's Guide for complete instructions on load and cycle for each STERIS V-PRO System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS – VPRO

STERIS V-PRO System Lumen Cycle	Intended Load
STERIS V-PRO 1 **STERIS V-PRO 1 Plus** **STERIS V-PRO maX** **STERIS V-PRO maX 2**	**STERIS V-PRO maX,** Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: - Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤500mm in length - Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length - Triple channeled devices with stainless steel lumens that are • ≥ 1.2 mm ID and ≤ 275 mm in length • ≥1.8 mm ID and ≤ 310 mm in length • or • ≥ 2.8 mm ID and ≤ 317 mm in length **STERIS V-PRO maX 2** • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: - Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤500mm in length - Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length - Triple channeled devices with stainless steel lumens that are • ≥ 1.2 mm ID and ≤ 275 mm in length • ≥1.8 mm ID and ≤ 310 mm in length or • ≥ 2.8 mm ID and ≤ 317 mm in length **STERIS V-PRO 1 STERIS V-PRO 1 Plus** The V-PRO 1 Cycle and the V-PRO 1 Plus Lumen Cycle can sterilize* instruments/devices with the following features: • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. • Medical devices with a single lumen with: - an inside diameter of 3 mm or larger and a length of 400 mm or shorter - an inside diameter of 2 mm or larger and a length of 250 mm or shorter - an inside diameter of 1 mm or larger and a length of 125 mm or shorter

TABLE 2: Validated Low Temperature Sterilization Products STERIS V-PRO 1, STERIS V-PRO 1 Plus, STERIS V-PRO maX, STERIS V-PRO maX 2, and STERIS V-PRO 60, Lumen[1] Cycles.

Note: Refer to the Manufacturer's User's Guide for complete instructions on load and cycle for each STERIS V-PRO System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS – VPRO

STERIS V-PRO System Lumen Cycle	Intended Load
STERIS V-PRO 60	The V-PRO 60 sterilizer's Lumen cycle can sterilize : • Instruments with diffusion- restricted spaces such as the hinged portion of forceps and scissors. • Non- Lumened devices including non- lumened rigid and semi-rigid endoscopes • Medical Devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ϒ Single or dual lumen devices with stainless steel lumens that are o ≥ 0.77 mm (~ 1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length ϒ Triple lumen devices with stainless steel lumens that are o ≥ 1.2 mm (~ 3/64") ID and ≤ 275 mm (~ 10 – 55/64") in length o ≥ 1.8 mm (~ 5/64") ID and ≤ 310 mm (~ 12 – 13/64") in length o or o ≥ 2.8 mm (~ 7/64") ID and ≤ 317 mm (~ 12 – 31/64") in length

1 The Non-Lumen articles can be processed in the Lumen cycle as it takes mixed loads

***TABLE 3: Validated Low Temperature Sterilization Products STERIS V-PRO 1 Plus, STERIS V-PRO maX, STERIS V-PRO maX 2, and STERIS V-PRO 60, Non-Lumen* Cycles** **Note: Refer to the User's Guide for complete instructions on load and cycle for each STERIS V-PRO System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS – VPRO**	
STERIS V-PRO System Non-Lumen Cycle	**Intended Load**
STERIS V-PRO 1 Plus **STERIS V-PRO maX** **STERIS V-PRO maX 2**	**STERIS V-PRO maX 2** Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes. **STERIS V-PRO maX** The Non-Lumen Cycle can sterilize instruments/devices with the following features: • Non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors. **STERIS V-PRO 1 Plus** The V-PRO 1 Plus Non-Lumen Cycle can sterilize instruments/devices with the following features: Non-Lumen instruments including non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.
STERIS V-PRO 60	The V-PRO 60 Non-Lumen Cycle can sterilize instruments/devices with the following features: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

***TABLE 4: Validated Low Temperature Sterilization Products STERIS V-PRO maX. STERIS V-PRO maX 2, and STERIS V-PRO 60, Flexible* Cycles Note: Refer to the User's Guide for complete instructions on load and cycle for each STERIS V-PRO System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS – VPRO**	
STERIS V-PRO System Flexible Cycle	**Intended Load**
STERIS V-PRO maX **STERIS V-PRO maX 2**	**STERIS V-PRO maX 2** **The Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) or bronchoscopes in either of two load configurations:** **1. Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load. The flexible endoscopes may contain either:** • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 998 mm in length And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length **2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. The flexible endoscopes may contain either:** • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length **STERIS V-PRO maX** **The Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) or bronchoscopes in either of two load configurations:** **1. Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load[3]. The flexible endoscopes my contain either:** • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 998 mm in length - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length **2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors[4]. The flexible endoscopes my contain either:** • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: - One lumen that is ≥ 1 mm ID and ≤ 998 mm in length - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

STERIS V-PRO 60	The V-PRO 60 sterilizer's 60 flexible cycle can sterilize: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: • Single or dual lumen device with lumens that are > 1 mm (~3/64") ID and <990 mm (38-63/34") in length

HALYARD Smart-Fold* Sterilization Wrap Recommendations for Use with Steris V-PRO low temperature sterilizer is provided in Table 1.5:

TABLE 5: Halyard Smart-Fold* Sterilization Wrap Recommendations[2] for Use with Steris V-PRO Sterilizer

SMART-FOLD* Sterilization Wrap Model	**Intended Loads[3]**	**Maximum Wrapped Package Content Weights [4]**						
		STERIS V-PRO® 1, V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Lumen	**STERIS V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Non-Lumen**	**STERIS V-PRO® maX V-PRO® maX 2 Flexible**	**STERIS V-PRO® 60 Lumen**	**STERIS V-PRO® 60 Non-Lumen**	**STERIS V-PRO® 60 Flexible**	**STERIS V-PRO® maX 2 Fast Non-Lumen[5]**
H450	Moderate to Heavyweight Package (for example: general use medical instruments)	13 lbs	13 lbs.	13 lbs.	11 lbs.	12 lbs.	The validation studies were conducted with one flexible endoscope packaged into a tray with silicone wrap, and instrument organizers and light cord (if not integral to scope) and no additional load.	N/A

SMART-FOLD* Sterilization Wrap Model	Intended Loads[3]	STERIS V-PRO® 1, V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Lumen	STERIS V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Non-Lumen	STERIS V-PRO® maX V-PRO® maX 2 Flexible	STERIS V-PRO® 60 Lumen	STERIS V-PRO® 60 Non-Lumen	STERIS V-PRO® 60 Flexible	STERIS V-PRO® maX 2 Fast Non-Lumen[5]
H650	Moderate to Heavyweight Package (for example: general use medical instruments)	19.65 lbs.	25 lbs.-max2, 19.65 – max, 1 and 1 plus	24 lbs.	11 lbs.	12 lbs.	The validation studies were conducted with one flexible endoscope packaged into a tray with silicone wrap, and instrument organizers and light cord (if not integral to scope) and no additional load.	N/A

[2]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 most appropriate for each intended use.

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

[4]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 for HALYARD SMART-FOLD* Sterilization Wraps.

[5]The Fast-Non-Lumen cycle is intended to sterilize pouched instruments trays only and is therefore not intended to be used for sterilization of HALYARD SMART-FOLD* Sterilization wraps.

DESCRIPTION OF DEVICE

HALYARD SMART-FOLD* Sterilization Wrap is supplied in bulk to the customer as pre-shaped sterilization wrap which is then used to wrap a medical device or a collection of medical devices for sterilization. The SMART-FOLD* Sterilization Wrap is comprised of two pre-shaped sheets of HALYARD* Sequential Sterilization Wrap. Each sheet is composed of a three-layer SMS (spunbond-meltblown-spunbond) polypropylene fabric treated with an antistatic treatment.
The SMART-FOLD* Sterilization Wrap features reinforcement zones, a medical device placement reference line, a white inner layer, side-tabs with closure strips and pull-tabs which allow for aseptic presentation of the sterilized medical device. The white sheet has the same material composition but contains no blue pigment.

The HALYARD SMART-FOLD* models and product codes for clearance with Steris Low Temperature Sterilization system (STERIS V-PRO® 1, V-PRO® 1 Plus®, V-PRO® maX, V-PRO® maX 2, STERIS V-PRO® 60) are listed below.

HALYARD 450 SMART-FOLD* Sterilization Wrap		
Product Code	**Size (in.)**	**Case Ct**
14324	22"x45"	72
14279	28”x46”	72
14268	40”x47”	48
14275	40”x55”	48
14313	48”x61”	48
HALYARD 650 SMART-FOLD* Sterilization Wrap		
14320	22"x45"	48
14281	28”x46”	48
14271	40”x47”	48
14277	40”x55”	48
14309	48”x61”	36

TECHNOLOGICAL CHARACTERISTICS COMPARISION:

Table 1.6: Technological Characteristics Comparison Table

Technological Characteristics	Proposed: HALYARD SMART-FOLD* Sterilization Wrap	Predicate: KIMGUARD* ONE-STEP* Sterilization Wrap (K142782)	Comparison to Predicate
Manufacturer	O&M Halyard. Inc	Halyard Health. Inc	Similar
Device Models	H450, H650	KC100, KC200, KC300, KC400, KC500, KC600	Similar
Regulation/Product Code	Sterilization Wrap: 880.6850 / FRG	Sterilization Wrap: 880.6850 / FRG	Same
Indications for Use	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 to maintain sterility of the enclosed device(s) until used.	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: V- PRO® 60 Low Temperature Sterilization System that includes: • Lumen Cycle • Non-Lumen Cycle • Flexible Cycle The KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.	Similar
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 rectangular sheets of KIMGUARD* Sterilization Wrap seemed on edges to allow convenient wrapping with two sheets simultaneously.	Similar
Sterilant	Vaporized Hydrogen Peroxide	Vaporized Hydrogen Peroxide	Same

Technological Characteristics	Proposed: HALYARD SMART-FOLD* Sterilization Wrap	Predicate: KIMGUARD* ONE-STEP* Sterilization Wrap (K142782)	Comparison to Predicate
Maintenance of Package Sterility	Passing 365 days Maintenance of Package Sterility results for all models of HALYARD SMART-FOLD* Sterilization wrap (H650, H450). STERIS V-PRO 1 = 365 days STERIS V-PRO 1 Plus = 365 days STERIS V-PRO maX = 365 days STERIS V-PRO 60 = 365 days STERIS V-PRO maX 2 = 365 days	Passing 365 days Maintenance of Package Sterility results for all models of KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600). STERIS V-PRO 60 = 365 days	Same
Sterilant Penetration	Passing results of sterilant penetration testing verified the sterilant penetrated the wrap effectively reached into the contents or instrument trays at half cycle condition. Achieved a 10^{-6} SAL following processing in a worst-case half-cycle.	Passing results of sterilant penetration testing verified the sterilant penetrated the wrap effectively reached into the contents or instrument trays at half cycle condition. Achieved a 10^{-6} SAL following processing in a worst-case half-cycle.	Same
Material Biocompatibility	10993-5: 2009 Biological evaluation of medical devices – Tests for in vitro cytotoxicity. Based on the conditions of this test: The device extract was found not to be cytotoxic. 10993-10:2010 Biological evaluation of medical devices –Tests for irritation and skin sensitization. Based on the conditions of this test: The polar and non-polar device extract was found not to be an irritant to the animal model used in the study.	ISO 10993-5: 2009 Biological evaluation of medical devices – Tests for in vitro cytotoxicity. Based on the conditions of this test: The device extract was found not to be cytotoxic.	Same. The proposed device was additionally tested with 10993-10:2010 Biological evaluation of medical devices – Tests for irritation and skin sensitization.

Physical Properties	The physical properties testing met the acceptance criteria and demonstrated passing results for the Halyard SMART-FOLD* (H450, H650) Sterilization wrap: • Bursting Properties of Fabrics – Part 2 – Pneumatic Method for Determination of Bursting Strength and Bursting Distension, ISO 13828-2:1999 • Determination of the permeability of fabrics (Air Permeability), ISO 9237:1995 E • Standard Test Method for Abrasion Resistance of Textile Fabrics (Martindale Abrasion Tester Method), ASTM D4966-12 • Standard Test Method for Mass Per Unit Area (Weight) of Fabric, ASTM D3776/D3776M-09a • Flame resistance requirements for Class I products of > 3.5 seconds flame travel, CPSC 16 CFR 1610:2007 • Water Resistance: Hydrostatic Pressure Test, AATCC-127 • Textiles – Test methods for nonwovens – Part 10: Lint and other particles generation in the dry state - Linting/Cleanliness, ISO 9073-10 • Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure, ASTM D5733-99 • Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test), ASTM D5034-95 • Test Method of Failure in Sewn Seams of Woven Fabrics, ASTM D1683/D1683M-11 • Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus, ASTM	The physical properties testing met the acceptance criteria and demonstrated passing results for the KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) Sterilization wrap: • Bacterial Filtration Efficiency (%) ASTM F2101:07 • Flammability CPSC 1610.4 (16 CFR Part 1610) • Hydrostatic Resistance (mbar) AATCC127-2008; WSP 80.6:2005 • Basis Weight (osy) ASTM D3776-07 • Mullen Burst (psi) ASTM D3786-06 • Grab Tensile Strength (lbf) ASTM D5034-09 • Trapezoid Tear Strength (lbf) ASTM D5733-99 • Abrasion Resistance - Martindale ASTM D4966-98 (re-aproved 2004) • Air Permeability Test (cfm) ISO 9237:1995 E • Tensile Strength and Elongation - Seam Test (gf) ASTM D1683-90a • Gelbo Lint (particles > 10 microns) WSP 160-1:2005	Similar
Technology/ Chemical composition	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. [SAME]	Same
Single Use Device	Yes	Yes **[SAME]**	Same

Table 1.7 Technological Characteristics Comparison Table

Component	Subject Device, K181959	Reference Device, K140963	Comparison to the Reference
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.	Same
Packaging	Bulk and Non-sterile	Bulk and Non-sterile	Same
Base Materials of Construction	Three-layer SMS (spunbond-meltblown-spunbond) fabric	Three-layer SMS (spunbond-meltblown-spunbond) fabric.	Same
Design	Two pre-shaped sheets of KIMGUARD* Sterilization Wrap, which include reinforcement strips, and seamed on edges to allow convenient wrapping with two sheets simultaneously	Two pre-shaped sheets of KIMGUARD Sterilization Wrap, which include reinforcement strips, and seamed on edges to allow convenient wrapping with two sheets simultaneously.	Same
Technology/ Chemical composition	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
Use	Single Use	Single Use	Same

Both the subject device and predicate device have similar indications for use statement, which is to enclose another medical device that is to be sterilized by a healthcare provider using Steris V-PRO Low sterilization system. The predicate 510(k) was cleared for use with Steris V-PRO 60 sterilizer under K142782. The remaining models, Steris V-PRO 1, Steris V-PRO 1 Plus and Steris V-PRO maX were cleared for use with KIMGUARD* One -Step sterilization by FDA under 510(k) submissions, k092167 and k112805.

The subject device, under this submission, HALYARD SMART-FOLD* Sterilization Wrap is the same as the reference devices which is cleared under K140963. Additionally, the HALYARD SMART-FOLD* Sterilization Wrap is comprised of the same material and composition as the base sheet of the Halyard ONE-STEP* sterilization wrap, which is the predicate device.

SUMMARY OF NONCLINICAL TESTS

Performance testing was conducted in accordance to the applicable requirements. Test results demonstrate that HALYARD SMART-FOLD* Sterilization Wrap (H450, H650), after sterilizing with the Steris V-PRO Low Temperature system (Models: V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX2 and V-PRO 60) maintains sterility until used.

Table 1.8: Sterilization Wrap Performance Tests

Study	Description	Results
Sterilant Penetration/Efficacy	The purpose of the sterilant penetration/Efficacy testing was to demonstrate sterilant penetration into instrument trays wrapped with Halyard SMART-FOLD* (H450, H650) Sterilization Wrap. The testing was performed using end of shelf life sterilant to demonstrate efficacy of the sterilant under half cycle condition in the V- PRO maX low temperature sterilizer, worst case lumen cycle.	The Halyard SMART-FOLD* (H450, H650) Sterilization wrap demonstrated effective sterilant penetration into instrument trays wrapped with Halyard Health SMART-FOLD* (H450, H650) Sterilization Wrap after processing in the V-PRO maX low temperature sterilizer under half cycle condition in the V- PRO maX low temperature sterilizer, worst case lumen cycle.
Maintenance of 365-Day Package Integrity	The purpose of the maintenance of Sterility testing was to demonstrate that the Halyard SMART-FOLD* (H450, H650) is an effective barrier for maintaining the sterility of various sterilization load for 30, 180, 365 days after processing in the worst-case V-Pro 60 Low Temperature Sterilizer Lumen cycle and followed by an event related shelf life study.	The Halyard SMART-FOLD* (H450, H650) Sterilization wrap demonstrated effective barrier using the simulated test pack for the best and worst-case weight wraps for maintaining the sterility of their contents for 30, 180, 365 days after processing in the worst-case V-PRO 60 Low Temperature Sterilizer Lumen cycle and followed by an event related shelf life study.
Material Biocompatibility	The purpose of the biocompatibility testing was to demonstrate that the Halyard SMART-FOLD* (H450, H650) is non-irritating and non- cytotoxic in accordance to Cytotoxicity,10993-5, Biological Evaluation of medical devices – Tests for invitro cytotoxicity and 10993 -10:2010, Biological Evaluation of medical devices – Tests for Irritation and Sensitization.	The Halyard SMART-FOLD* (H450, H650) Sterilization wrap was found to be non-cytotoxic and non-irritant based on the conditions of these tests.

Study	Description	Results
Physical properties	The purpose of the physical properties testing was to demonstrate passing results for the following physical properties for Halyard SMART-FOLD* (H450, H650) wrap: • Bursting Properties of Fabrics – Part 2 – Pneumatic Method for Determination of Bursting Strength and Bursting Distension, ISO 13828-2:1999 • Determination of the permeability of fabrics (Air Permeability), ISO 9237:1995 E • Standard Test Method for Abrasion Resistance of Textile Fabrics (Martindale Abrasion Tester Method), ASTM D4966-12 • Standard Test Method for Mass Per Unit Area (Weight) of Fabric, ASTM D3776/D3776M-09a • Flame resistance requirements for Class I products of > 3.5 seconds flame travel, CPSC 16 CFR 1610:2007 • Water Resistance: Hydrostatic Pressure Test, AATCC-127 • Textiles – Test methods for nonwovens – Part 10: Lint and other particles generation in the dry state - Linting/Cleanliness**,** ISO 9073-10 • Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure, ASTM D5733-99 • Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)**,** ASTM D5034-95 • Test Method of Failure in Sewn Seams of Woven Fabrics**,** ASTM D1683/D1683M-11 • Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of	The physical properties testing met the acceptance criteria and demonstrated passing results for the Halyard SMART-FOLD* (H450, H650) Sterilization wrap.

	Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus, ASTM F2101	

In summary, testing was conducted to evaluate the performance of the HALYARD SMART-FOLD* when used with Steris Low temperature system, including chemical composition, physical properties, sterilant penetration/efficacy, maintenance of package integrity and biocompatibility tests that have passed and met the acceptance criteria. Therefore, the passing results from above sterilant penetration, maintenance of package integrity, biocompatibility and the physical properties demonstrate that the device met the acceptance criteria and the specification for the performance test for the subject device, HALYARD SMART-FOLD* when used with Steris V-PRO Low sterilization system (Models STERIS V-PRO 60, STERIS V-PRO maX, STERIS V-PRO maX 2, STERIS V-PRO 1, STERIS V-PRO 1 Plus).

Conclusion

Based on the intended use, technological characteristics, performance data and nonclinical tests performed, the subject HALYARD SMART-FOLD*Sterilization Wrap (H450, H650) is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K142782.