July 2, 2026

O & M Halyard, Inc.
Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k, Saint Paul, MN 55114 USA
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Re: K261897
Trade/Device Name: HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY*Technology, HALYARD* STANDARDFLEX* Sterilization Wrap with ASSURE-DRY* Technology, and HALYARD* H300W Sterilization Wrap with ASSURE-DRY* Technology
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: FRG
Dated: June 5, 2026
Received: June 5, 2026

Dear Prithul Bom:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.07.02 12:23:52 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261897

Device Name
HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology; HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology; HALYARD* STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology; HALYARD* H300W Sterilization Wrap with ASSURE-DRY* Technology

Indications for Use *(Describe)*

HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, and H300W Sterilization Wrap with ASSURE-DRY* Technology are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

• Pre-vacuum steam
• The wrap was validated for dry times of 20 minutes with the moisture managing amber layer on the inside, and for 30 minutes with the moisture managing amber layer on the outside.
• 270°F/132°C for 4 minutes
• 270°F/132°C for 10 minutes
• 273.2°F/134°C for 3 minutes
• 273.2°F/134°C for 18 minutes
• 275°F/135°C for 3 minutes

• STERIS V-PRO® Low Temperature Sterilization Systems. The wrap was validated to be effectively aerated during the pre-programmed cycles.
• STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles)
• STERIS V-PRO® s2 (Lumen, Non-Lumen and Flexible Cycles)
• STERIS V-PRO® maX (Lumen, Non-Lumen and Flexible Cycles)
• STERIS V-PRO® maX 2 (Lumen, Non-Lumen and Flexible Cycles)

• Advanced Sterilization Products STERRAD® Sterilization System
• STERRAD® 100NX® (Standard Cycle)
• STERRAD® 100NX® with ALLClear® Technology (Standard Cycle)

Validated Loads1,2

Sterilization Cycle: Pre-Vacuum Cycle3
Wrapped Package Content Weight ARMOR-FLEX: 25 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: ASP STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle4
Wrapped Package Content Weight ARMOR-FLEX: 10.7 lbs
Wrapped Package Content Weight HEAVY-FLEX: 10.7 lbs
Wrapped Package Content Weight STANDARD-FLEX: 10.7 lbs
Wrapped Package Content Weight H300W: 10.7 lbs

Sterilization Cycle: STERIS V-PRO maX, maX 2 Lumen Cycle4

Wrapped Package Content Weight ARMOR-FLEX: 19.65 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO 60, V-PRO s2 Lumen Cycle4
Wrapped Package Content Weight ARMOR-FLEX: 11 lbs
Wrapped Package Content Weight HEAVY-FLEX: 11 lbs
Wrapped Package Content Weight STANDARD-FLEX: 11 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO maX, maX 2 Non-Lumen Cycle4
Wrapped Package Content Weight ARMOR-FLEX: 25 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO 60, V-PRO s2 Non-Lumen Cycle4
Wrapped Package Content Weight ARMOR-FLEX: 25 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO maX, maX 2 Flexible Cycle4
Wrapped Package Content Weight ARMOR-FLEX: 24 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO 60, V-PRO s2 Flexible Cycle4
Wrapped Package Content Weight ARMOR-FLEX: 11 lbs
Wrapped Package Content Weight HEAVY-FLEX: 11 lbs
Wrapped Package Content Weight STANDARD-FLEX: 11 lbs
Wrapped Package Content Weight H300W: 9 lbs

1 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.

2 It is recommended to not exceed the maximum wrapped package content weights.

3 Stainless steel instrument tray (~2 lbs.) containing lightweight medical instrumentation made of various metals and polymers, including hinged/mated and serrated/knurled surfaces or lumens (lumen length ≤ 200 mm and lumen inner diameter ≥ 2.5 mm and ≤ 4.0 mm) compatible with moist heat sterilization and four (4) Huck towels, as shown in the information above. HALYARD Tray Liner and Transport Tray has been validated with the pre-vacuum steam cycle.

4 Reference Validation Load information below

Validation Load Composition
ASP STERRAD® 100NX® and 100NX® with ALLClear Technology Standard Cycle Validation Load
Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:
- An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless

steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle.)
Refer to the STERRAD® 100NX® Sterilizer User's Guide and STERRAD® 100NX® with ALLClear® Technology Sterilizers User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 21.4 lbs. per load).

STERIS V-PRO maX and STERIS V-PRO maX2 Lumen Cycle Intended Load
†Medical devices with the following configurations:
• Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Single, dual or triple channeled devices with stainless steel lumens with
• An inside diameter of 0.77 mm or larger and a length of 527 mm or shorter
• An inside diameter of 0.8 mm or larger and a length of 542 mm or shorter
• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
• Dead end lumen with
• An inside diameter of 1.3 mm or larger and a length of 73 mm or shorter
• Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) with
• An inside diameter of 3 mm or larger and a length of 298 mm or shorter
• An inside diameter of 4 mm or larger and a length of 424 mm or shorter
† Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs.

STERIS V-PRO 60 and s2 Lumen Cycle Intended Load
Metal and non-metal medical devices including instruments with diffusion-restricted spaces (such as the hinged portion of forceps or scissors) and single, dual or triple channeled rigid/semi-rigid endoscopes, with the following configurations:
• Single or dual channeled devices with stainless steel lumens with:
• An inside diameter of 0.77 mm or larger and a length of 410 mm or shorter
• An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter
• Triple channeled devices with stainless steel lumens with:
• An inside diameter of 1.2 mm or larger and a length of 275 mm or shorter
• An inside diameter of 1.8 mm or larger and a length of 310 mm or shorter
• An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter
Total load weight restricted to 11lbs.

STERIS V-PRO maX and STERIS V-PRO maX2 Non-Lumen Cycle Intended Load
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Note: The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

STERIS® V-PRO® 60 and s2 Non-Lumen Cycle Intended Load
Metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid and flexible endoscopes and medical devices with diffusion-restricted spaces such as the hinged portion of forceps or scissors.
Total load weight is restricted to 25lbs.

STERIS V-PRO maX and STERIS V-PRO maX 2 Flexible Cycle Intended Load
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical

Care) and bronchoscopes in either of the two configurations:
Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.*
The flexible endoscopes may contain single or dual channel lumens that have:
• An inside diameter of 1 mm or larger and a length of 1050 mm or shorter
OR
• One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat and additional non-lumened instruments.** The flexible endoscope may contain single or dual channel lumens that have:
• An inside diameter of 1 mm or larger and a length of 1050 mm or shorter
Additional instruments may include non-lumened or lumened medical devices with the following configurations:
Single, dual or triple channel stainless steel lumen that have:
• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
** The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs.

STERIS V-PRO 60 and s2 Flexible Cycle Intended Load
Load 1:
Single or dual channeled Flexible Surgical Endoscopes or Bronchoscopes with lumens that have:
• An inside diameter of 1 mm or larger and a length of 990 mm or shorter.
Load 2*:
Non-lumened instrument, instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors, and medical devices containing stainless steel lumens with the following dimensions:
• An inside diameter of 0.76 mm or larger and a length of 233 mm or shorter
• An inside diameter of 1.0 mm or larger and a length of 254 mm or shorter
• An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter
*Additional stainless steel lumens are restricted to 12 lumens
Total load weight is restricted to 11 lbs.

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 – K261897

Submitter:	O&M Halyard, Inc. 1220 Old Alpharetta Rd, Suite 320 Alpharetta, GA 30005 Phone: 804-723-7000/800-488-8850 Fax: 804-723-7100
Regulatory Contact:	Anureet Singh Regulatory Affairs Manager
Date of Summary:	24 June 2026
Device Trade Name:	HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, and HALYARD* H300W Sterilization Wrap with ASSURE-DRY* Technology
Common Name:	Sterilization Wrap
Classification Name:	Sterilization wrap (21 CFR 880.6850, Product Code FRG)
Predicate Device:	K234050 (HALYARD* ONE-STEP* Sterilization Wrap, HALYARD* QUICK CHECK* Sterilization Wrap, and HALYARD* SEQUENTIAL Sterilization Wrap)
Device Description:	The HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, and HALYARD* H300W Sterilization Wrap with ASSURE-DRY* Technology are comprised of one sheet of STEEL BLUE* and one sheet of amber contrasting layers ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously and aseptic presentation. The HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, and HALYARD* H300W Sterilization Wrap with ASSURE-DRY* Technology are intended to enclose another medical device that is to be sterilized by a healthcare provider.

Indications for Use for ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, and H300W Sterilization Wrap with ASSURE-DRY* Technology

HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, and H300W Sterilization Wrap with ASSURE-DRY* Technology are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

- Pre-vacuum steam
    - The wrap was validated for dry times of 20 minutes with the moisture managing amber layer on the inside, and for 30 minutes with the moisture managing amber layer on the outside.
    - 270°F/132°C for 4 minutes
    - 270°F/132°C for 10 minutes
    - 273.2°F/134°C for 3 minutes
    - 273.2°F/134°C for 18 minutes
    - 275°F/135°C for 3 minutes

- STERIS V-PRO® Low Temperature Sterilization Systems. The wrap was validated to be effectively aerated during the pre-programmed cycles.
    - STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles)
    - STERIS V-PRO® s2 (Lumen, Non-Lumen and Flexible Cycles)
    - STERIS V-PRO® maX (Lumen, Non-Lumen and Flexible Cycles)
    - STERIS V-PRO® maX 2 (Lumen, Non-Lumen and Flexible Cycles)

- Advanced Sterilization Products STERRAD® Sterilization System
    - STERRAD® 100NX® (Standard Cycle)
    - STERRAD® 100NX® with ALLClear® Technology (Standard Cycle)

Validated Loads[1,2]

Sterilization Cycle: Pre-Vacuum Cycle[3]
Wrapped Package Content Weight ARMOR-FLEX: 25 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: ASP STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle[4]
Wrapped Package Content Weight ARMOR-FLEX: 10.7 lbs
Wrapped Package Content Weight HEAVY-FLEX: 10.7 lbs
Wrapped Package Content Weight STANDARD-FLEX: 10.7 lbs
Wrapped Package Content Weight H300W: 10.7 lbs

Sterilization Cycle: STERIS V-PRO maX, maX 2 Lumen Cycle[4]
Wrapped Package Content Weight ARMOR-FLEX: 19.65 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO 60, V-PRO s2 Lumen Cycle[4]
Wrapped Package Content Weight ARMOR-FLEX: 11 lbs
Wrapped Package Content Weight HEAVY-FLEX: 11 lbs
Wrapped Package Content Weight STANDARD-FLEX: 11 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO maX, maX 2 Non-Lumen Cycle[4]
Wrapped Package Content Weight ARMOR-FLEX: 25 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO 60, V-PRO s2 Non-Lumen Cycle[4]
Wrapped Package Content Weight ARMOR-FLEX: 25 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO maX, maX 2 Flexible Cycle[4]
Wrapped Package Content Weight ARMOR-FLEX: 24 lbs
Wrapped Package Content Weight HEAVY-FLEX: 17 lbs
Wrapped Package Content Weight STANDARD-FLEX: 13 lbs
Wrapped Package Content Weight H300W: 9 lbs

Sterilization Cycle: STERIS V-PRO 60, V-PRO s2 Flexible Cycle[4]
Wrapped Package Content Weight ARMOR-FLEX: 11 lbs
Wrapped Package Content Weight HEAVY-FLEX: 11 lbs
Wrapped Package Content Weight STANDARD-FLEX: 11 lbs
Wrapped Package Content Weight H300W: 9 lbs

[1] 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.

[2] It is recommended to not exceed the maximum wrapped package content weights.

[3] Stainless steel instrument tray (~2 lbs.) containing lightweight medical instrumentation made of various metals and polymers, including hinged/mated and serrated/knurled surfaces or lumens (lumen and four (4) Huck towels, as shown in the information above. HALYARD Tray Liner and Transport Tray has been validated with the pre-vacuum steam cycle.

[4] Reference Validation Load information is below.

Validation Load Composition

ASP STERRAD® 100NX® and 100NX® with ALLClear Technology Standard Cycle Validation Load Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:
- An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle.)

Refer to the STERRAD® 100NX® Sterilizer User's Guide and STERRAD® 100NX® with ALLClear® Technology Sterilizers User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 21.4 lbs. per load).

STERIS V-PRO maX and STERIS V-PRO maX2 Lumen Cycle Intended Load

†Medical devices with the following configurations:

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Single, dual or triple channeled devices with stainless steel lumens with
- An inside diameter of 0.77 mm or larger and a length of 527 mm or shorter
- An inside diameter of 0.8 mm or larger and a length of 542 mm or shorter
- An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
- Dead end lumen with
- An inside diameter of 1.3 mm or larger and a length of 73 mm or shorter
- Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) with
- An inside diameter of 3 mm or larger and a length of 298 mm or shorter
- An inside diameter of 4 mm or larger and a length of 424 mm or shorter

† Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs.

STERIS V-PRO 60 and s2 Lumen Cycle Intended Load

Metal and non-metal medical devices including instruments with diffusion-restricted spaces (such as the hinged portion of forceps or scissors) and single, dual or triple channeled rigid/semi-rigid endoscopes, with the following configurations:

- Single or dual channeled devices with stainless steel lumens with:
- An inside diameter of 0.77 mm or larger and a length of 410 mm or shorter
- An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter
- Triple channeled devices with stainless steel lumens with:
- An inside diameter of 1.2 mm or larger and a length of 275 mm or shorter
- An inside diameter of 1.8 mm or larger and a length of 310 mm or shorter
- An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter Total load weight restricted to 11lbs.

STERIS V-PRO maX and STERIS V-PRO maX2 Non-Lumen Cycle Intended Load

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Note: The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

STERIS® V-PRO® 60 and s2 Non-Lumen Cycle Intended Load

Metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid and flexible endoscopes and medical devices with diffusion-restricted spaces such as the hinged portion of forceps or scissors. Total load weight is restricted to 25lbs.

STERIS V-PRO maX and STERIS V-PRO maX 2 Flexible Cycle Intended Load

Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:
Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain single or dual channel lumens that have:

- An inside diameter of 1 mm or larger and a length of 1050 mm or shorter OR
- One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat and additional non-lumened instruments.** The flexible endoscope may contain single or dual channel lumens that have:
- An inside diameter of 1 mm or larger and a length of 1050 mm or shorter

Additional instruments may include non-lumened or lumened medical devices with the following configurations:
Single, dual or triple channel stainless steel lumen that have:

- An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter

* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
** The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs.

STERIS V-PRO 60 and s2 Flexible Cycle Intended Load Load 1:
Single or dual channeled Flexible Surgical Endoscopes or Bronchoscopes with lumens that have:

- An inside diameter of 1 mm or larger and a length of 990 mm or shorter. Load 2*:

Non-lumened instrument, instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors, and medical devices containing stainless steel lumens with the following dimensions:

- An inside diameter of 0.76 mm or larger and a length of 233 mm or shorter
- An inside diameter of 1.0 mm or larger and a length of 254 mm or shorter
- An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter

*Additional stainless steel lumens are restricted to 12 lumens
Total load weight is restricted to 11 lbs.

Technological Characteristics Comparison Table:

	Subject **HALYARD* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX* and H300W Sterilization Wrap with ASSURE-DRY* Technology (K261897)**	**Predicate** **HALYARD ONE-STEP, QUICK CHECK, and SEQUENTIAL Sterilization Wrap (K234050)**	**Comparison**
Manufacturer	O&M Halyard, Inc.	O&M Halyard, Inc.	Same
Device Model Identifier	HALYARD® ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology, HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology. STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology and H300W Sterilization Wrap with ASSURE-DRY* Technology	HALYARD ONE-STEP, QUICK CHECK, and SEQUENTIAL H100 H200 H300 H400 H500 H600	Different
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
Intended Use	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) until used.	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) until used.	Same
Indication for Use	HALYARD* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX* and H300W Sterilization Wrap with ASSURE-DRY* Technology are intended to enclose another medical device that is to be sterilized by a healthcare provider (Refer to pages 2 to 5 for complete Indications For Use)	HALYARD ONE-STEP, QUICK CHECK and SEQUENTIAL Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider	Similar; the subject device has different names.
Validated Sterilization Cycles	• Pre-vacuum steam: o 270°F/132°C for 4 minutes o 270°F/132°C for 10 minutes o 273.2°F/134°C for 3 minutes o 273.2°F/134°C for 18 minutes o 275°F/135°C for 3 minutes	• Pre-vacuum steam (270°F/132°C for 4 minutes) • 100% ethylene oxide (EO) (concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes)	Similar; the subject device includes steam, STERIS V-PRO and STERRAD 100NX Standard cycle claims.

	Subject **HALYARD* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX* and H300W Sterilization Wrap with ASSURE-DRY* Technology (K261897)**	**Predicate** **HALYARD ONE-STEP, QUICK CHECK, and SEQUENTIAL Sterilization Wrap (K234050)**	**Comparison**
Validated Sterilization Cycles	STERIS V-PRO® Low Temperature Sterilization System: o STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles) o STERIS V-PRO® s2 (Lumen, Non-Lumen and Flexible Cycles) o STERIS V-PRO® maX (Lumen, Non-Lumen and Flexible Cycle) STERIS V-PRO® maX 2 (Lumen, Non-Lumen and Flexible Cycle) ASP Sterilization Products STERRAD Sterilization System: o STERRAD® 100NX® (Standard Cycle) o STERRAD® 100NX® with ALLClear® Technology, (Standard Cycle)	• Pre-vacuum steam (270°F/132°C for 4 minutes) • 100% ethylene oxide (EO) (concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes) V-PRO® Low Temperature Sterilization System: o Lumen Cycle o Non-Lumen Cycle o Flexible Cycle • STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles) • STERIS V-PRO® s2 (Lumen, Non-Lumen and Flexible Cycles) • STERIS V-PRO® 1 (Lumen Cycle) • STERIS V-PRO® 1 Plus (Lumen and Non-Lumen Cycle) • STERIS V-PRO® maX (Lumen, Non-Lumen and Flexible Cycle) • STERIS V-PRO® maX 2 (Lumen, Non-Lumen and Flexible Cycle) • STERRAD® 50, 100S, and 200 • STERRAD® NX®, (Standard Cycle, Advanced Cycle) • STERRAD® NX® with ALLClear® Technology, (Standard Cycle, Advanced Cycle) • STERRAD® 100NX® (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle) • STERRAD® 100NX® with ALLClear® Technology, (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle, (ULTRA GI SMART-FOLD only)) • STERILUCENT® HC80TT Sterilization Cycles (Lumen and Flexible Cycles) HALYARD ONE-STEP, QUICK-CHECK, and SEQUENTIAL additionally includes: • Stryker Sterizone VP4 Sterilizer Cycle 1 • Gravity steam (250°F/121°C for 30 minutes) HALYARD SMART-FOLD additionally includes: • STERRAD® 100NX® (ULTRA GI Cycle)	Similar; the subject device includes steam, STERIS V-PRO and STERRAD 100NX Standard cycle claims.

	Subject **HALYARD* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX* and H300W Sterilization Wrap with ASSURE-DRY* Technology (K261897)**	**Predicate** **HALYARD ONE-STEP, QUICK CHECK, and SEQUENTIAL Sterilization Wrap (K234050)**	**Comparison**
Dry Time	20 minutes - with the moisture managing amber layer on the inside. 30 minutes - with the moisture managing amber layer on the outside.	20 minutes - H100, H200 30 minutes - H300, H400, H500, H600	Different; the subject device layer can be configured for 20 or 30 minute dry time.
Maintenance of Sterility/ Package Integrity	12 months	12 months	Same
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).	HALYARD ONE-STEP and QUICK CHECK 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). HALYARD SEQUENTIAL A sheet of nonwoven polypropylene fabric composed of three thermally-bonded layers consisting of a meltblown polypropylene layer surrounded by spunbond polypropylene layers (SMS).	Similar; the subject device is only a two sheet design.

	Subject **HALYARD* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX* and H300W Sterilization Wrap with ASSURE-DRY* Technology (K261897)**	**Predicate** **HALYARD ONE-STEP, QUICK CHECK, and SEQUENTIAL Sterilization Wrap (K234050)**	**Comparison**
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 STEEL BLUE* and amber pigments. The amber layer includes a moisture management technology.	Polypropylene with blue and white pigments	Different; the subject device includes a moisture management layer.
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* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX* and H300W Sterilization Wrap with ASSURE-DRY* Technology was evaluated and the results showed that acceptance criteria were met demonstrating that the subject device allows sterilization of its contents using Pre-Vacuum Steam Sterilization, STERIS V-PRO Low Temperature Sterilization Systems and ASP STERRAD 100NX Standard Cycle and that sterility is maintained for the testing period of 12 months.

Purpose	**Test**	**Acceptance Criteria**	**Results**
Sterilant Penetration/Efficacy	ANSI/AAMI ST79 ANSI/AAMI/ISO 11138-7 ANSI/AAMI/ISO 22441	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 16 CFR Part 1610	Complies with the design requirements for selected physical properties	Passed
Maintenance of Sterility/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 10993-23	Non-cytotoxic Non-irritating	Passed
Residuals	Steris V-PRO Low Temperature Sterilization System H_2O_2 residuals ASP STERRAD 100NX Low Temperature Sterilization System H_2O_2 residuals	Met predetermined limits	Passed

Performance Testing (Clinical):	Clinical evaluations were not required and therefore are not submitted with this 510(k).
Discussion:	The HALYARD* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX*, and H300W Sterilization Wrap with ASSURE-DRY* Technology in this submission and the predicate device 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 subject device and the predicate device have identical intended use and the differences in technological characteristics, that is, the Device Model Identifiers, Indications For Use, Sterilization Parameters, and Materials do not affect the performance 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 subject device HALYARD* ARMOR-FLEX*, HEAVY-FLEX*, STANDARD-FLEX*, and H300W Sterilization Wrap with ASSURE-DRY* Technology is as safe, as effective and performs as well as or better than the legally marketed predicate HALYARD ONE-STEP, QUICK CHECK and SEQUENTIAL Sterilization Wrap under K234050.