October 28, 2026

O&M Halyard, Inc.
Natrisya Nur Abdul Rahman
RA Specialist
1220 Old Alpharetta Rd.
Suite 320
Alpharetta, Georgia 30005

Re: K260310
Trade/Device Name: HALYARD* CHEMO360 Procedure Gown Tested for use with Chemotherapy Drugs (L, XXL); HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs (L, XXL)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: QSO
Dated: September 29, 2026
Received: September 29, 2026

Dear Natrisya Nur Abdul Rahman:

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.

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

BIFENG QIAN -S

Bifeng Qian, M.D., Ph.D.
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)*
K260310

Device Name
HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs (L, XXL);
HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs (L, XXL)

Indications for Use *(Describe)*
HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs and HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs are non-sterile, disposable, single-use AAMI PB70 Level 2 Procedure Gown worn by healthcare workers for minimal to low fluid contact situations involving water, blood, bodily fluids, or other fluids for general infection control and/or staff protection. Also, can be worn by healthcare workers during the administration of chemotherapy drugs to patients.

Both the HALYARD* CHEMO360* Procedure Gown Tested for Use with Chemotherapy Drugs and the HALYARD* Procedure Gown Tested for Use with Chemotherapy Drugs were evaluated for resistance to permeation by selected chemotherapy drugs in accordance with ASTM F3267, Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy Drugs, using ASTM F739, Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact. The gowns meet the requirements for Part A: Selective Protection under ASTM F3267 based on the chemotherapy drug permeation testing conducted. Chemotherapy drug permeation resistance was reported as the average standardized breakthrough time over a 480-minute test period:

Arsenic Trioxide (Trisenox), 1 mg/mL (1,000 ppm)
Azacytidine (Vidaza), 25 mg/mL (25,000 ppm)
Bendamustine HCl, 25 mg/mL (25,000 ppm)
Bleomycin Sulfate, 15 mg/mL (15,000 ppm)
Bortezomib, 1 mg/mL (1,000 ppm)
Busulfan, 6 mg/mL (6,000 ppm)
Carboplatin, 10 mg/mL (10,000 ppm)
Car lzomib, 2 mg/mL (2,000 ppm)
Carmustine, 3.3 mg/mL (3,300 ppm)
Cladribine, 1 mg/mL (1,000 ppm)
Cyclosporin A, 100 mg/mL (100,000 ppm)
Cytovene (Ganciclovir), 10 mg/mL (10,000 ppm)
Dacarbazine (DTIC), 10 mg/mL (10,000 ppm)
Dactinomycin, 0.5 mg/mL (500 ppm)
Daunorubicin HCl, 5 mg/mL (5,000 ppm)
Decitabine, 5 mg/mL (5,000 ppm)
Docetaxel, 10 mg/mL (10,000 ppm)
Doxorubicin HCl, 2 mg/mL (2,000 ppm)
Epirubicin HCl (Ellence), 2 mg/mL (2,000 ppm)
Eribulin Mesylate, 0.5 mg/mL (500 ppm)
Fluorouracil (Adrucil), 50 mg/mL (50,000 ppm)
Gemcitabine HCL, 38 mg/mL (38,000 ppm)
Idarubicin HCL, 1 mg/mL (1,000 ppm)
Lenvatinib, 20 mg/mL (20,000 ppm)
Leuprolide acetate salt, 5 mg/mL (5,000 ppm)
Mechlorethamine HCl, 1 mg/mL (1,000 ppm)
Melphalan HCl, 5 mg/mL (5,000 ppm)
Methotrexate, 25 mg/mL (25,000 ppm)

Mitomycin C, 0.5 mg/mL (500 ppm)
Mitoxantrone HCl, 2 mg/mL (2,000 ppm)
Oxaliplatin, 5 mg/mL (5,000 ppm)
Pemetrexed, 25 mg/mL (25,000 ppm)
Raltitrexed, 0.5 mg/mL (500 ppm)
Retrovir, 10 mg/mL (10,000 ppm)
Rituximab, 10 mg/mL (10,000 ppm)
Sorafenib Tosylate, 200 mg/mL (200,000 ppm)
Tamoxifen, 2 mg/mL (2,000 ppm)
Thiotepa, 10 mg/mL (10,000 ppm)
Topotecan HCL, 1 mg/mL (1,000 ppm)
Vinblastine Sulfate, 1 mg/mL (1,000 ppm)
Vinorelbine, 10 mg/mL (10,000 ppm)

Caution:
The following chemotherapy drugs and concentration showed breakthrough detected in less than 480 minutes:

Cytarabine (Cytosine), 100 mg/ml (100,000 ppm)	60 minutes
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	<30 minutes
Fludarabine, 25 mg/ml (25,000 ppm)	120 minutes
lfosfamide, 50 mg/ml (50,000 ppm)	30 minutes
lrinotecan HCI, 20 mg/ml (20,000 ppm)	240 minutes
Paclitaxel, 6 mg/ml (6,000 ppm)	120 minutes
Vincristine sulfate, 1 mg/ml (1,000 ppm)	<30 minutes

Per ASTM F3267-22, the following chemotherapy drugs had the following breakthrough at the Standard Breakthrough Rate of 0.1µg/cm2/minute:
Cyclophosphamide, at a concentration of 20 mg/mL (20,000 ppm), demonstrated a breakthrough detection time of 120 minutes. The cumulative permeation was 0.00 µg/cm² at 30 minutes, 0.00 µg/cm² at 60 minutes, and 516.00 µg/cm² at 240 minutes.

Cytarabine HCl (Cytosine), at a concentration of 100 mg/mL (100,000 ppm), demonstrated a breakthrough detection time of 60 minutes. The cumulative permeation was 0.26 µg/cm² at 30 minutes, 0.46 µg/cm² at 60 minutes, and 68.35 µg/cm² at 240 minutes.

Fludarabine, at a concentration of 25 mg/mL (25,000 ppm), demonstrated a breakthrough detection time of 120 minutes. The cumulative permeation was 0.08 µg/cm² at 30 minutes, 0.27 µg/cm² at 60 minutes, and 7.28 µg/cm² at 240 minutes.

Irinotecan HCl, at a concentration of 20 mg/mL (20,000 ppm), demonstrated a breakthrough detection time of 240 minutes. The cumulative permeation was 0.03 µg/cm² at 30 minutes, 0.10 µg/cm² at 60 minutes, and 0.30 µg/cm² at 240 minutes.

Paclitaxel (Taxol), at a concentration of 6 mg/mL (6,000 ppm), demonstrated a breakthrough detection time of 120 minutes. The cumulative permeation was 0.00 µg/cm² at 30 minutes, 0.00 µg/cm² at 60 minutes, and 1.64 µg/cm² at 240 minutes.

The following hazardous drugs (opioids) and concentration had NO breakthrough detected within 480 minutes:
Fentanyl Citrate Injection, 100 mcg/2 ml
Fentanyl Citrate Injection / Simulated Gastric Acid Fluid Mix, 50/50 solution

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

510(k) Number:	K260310
Date Prepared:	October 27, 2026
Submitter:	O&M Halyard Inc. 1220 Old Alpharetta Road, Suite 320 Alpharetta, GA 30005
Regulatory Contact:	Natrisya Nur natrisya.nur@owens-minor.com
Device Trade Names:	HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs (L, XXL) HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs (L, XXL)
Device Common Name:	Procedure Gown
FDA Device Product Code:	QSO
FDA Device Classification:	Class II
FDA Regulation Number:	21 CFR 878.4040
Predicate Device:	K230135 Copioumed Chemotherapy Isolation Gown

Device Descriptions:

The HALYARD* CHEMO360* Procedure Gown Tested for Use with Chemotherapy Drugs is a blue, full-back, non-sterile, single-use disposable gown available in sizes L and XXL. The gown is constructed of polypropylene fabric laminated with a polypropylene-polyethylene film and features a neck tape closure, front tie, and knit cuffs.

The HALYARD* Procedure Gown Tested for Use with Chemotherapy Drugs is a blue, open-back, non-sterile, single-use disposable gown available in sizes L and XXL. The gown is constructed of polypropylene fabric laminated with a polypropylene-polyethylene film and features an over-the-head design with knit cuffs.

Indications for Use

HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs and HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs are non-sterile, disposable, single-use, AAMI PB70 Level 2 Procedure Gowns worn by healthcare workers for minimal to low fluid contact situations involving water, blood, bodily fluids, or other fluids for general infection control and/or staff protection. Also, can be worn by healthcare workers during the administration of chemotherapy drugs to patients.

Both the HALYARD* CHEMO360* Procedure Gown Tested for Use with Chemotherapy Drugs and the HALYARD* Procedure Gown Tested for Use with Chemotherapy Drugs were evaluated for resistance to permeation by selected chemotherapy drugs in accordance with ASTM F3267, *Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy Drugs*, using ASTM F739, *Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact*. The gowns meet the requirements for Part A: Selective Protection under ASTM F3267 based on the chemotherapy drug permeation testing conducted**.**

Chemotherapy drug permeation resistance was reported as the average standardized breakthrough time over a 480-minute test period:
Arsenic Trioxide (Trisenox), 1 mg/mL (1,000 ppm)
Azacytidine (Vidaza), 25 mg/mL (25,000 ppm)
Bendamustine HCl, 25 mg/mL (25,000 ppm)
Bleomycin Sulfate, 15 mg/mL (15,000 ppm)
Bortezomib, 1 mg/mL (1,000 ppm)
Busulfan, 6 mg/mL (6,000 ppm)
Carboplatin, 10 mg/mL (10,000 ppm)
Car lzomib, 2 mg/mL (2,000 ppm)
Carmustine, 3.3 mg/mL (3,300 ppm)
Cladribine, 1 mg/mL (1,000 ppm)
Cyclosporin A, 100 mg/mL (100,000 ppm)
Cytovene (Ganciclovir), 10 mg/mL (10,000 ppm)
Dacarbazine (DTIC), 10 mg/mL (10,000 ppm)
Dactinomycin, 0.5 mg/mL (500 ppm)
Daunorubicin HCl, 5 mg/mL (5,000 ppm)
Decitabine, 5 mg/mL (5,000 ppm)
Docetaxel, 10 mg/mL (10,000 ppm)
Doxorubicin HCl, 2 mg/mL (2,000 ppm)

Epirubicin HCl (Ellence), 2 mg/mL (2,000 ppm)
Eribulin Mesylate, 0.5 mg/mL (500 ppm)
Fluorouracil (Adrucil), 50 mg/mL (50,000 ppm)
Gemcitabine HCL, 38 mg/mL (38,000 ppm)
Idarubicin HCL, 1 mg/mL (1,000 ppm)
Lenvatinib, 20 mg/mL (20,000 ppm)
Leuprolide acetate salt, 5 mg/mL (5,000 ppm)
Mechlorethamine HCl, 1 mg/mL (1,000 ppm)
Melphalan HCl, 5 mg/mL (5,000 ppm)
Methotrexate, 25 mg/mL (25,000 ppm)
Mitomycin C, 0.5 mg/mL (500 ppm)
Mitoxantrone HCl, 2 mg/mL (2,000 ppm)
Oxaliplatin, 5 mg/mL (5,000 ppm)
Pemetrexed, 25 mg/mL (25,000 ppm)
Raltitrexed, 0.5 mg/mL (500 ppm)
Retrovir, 10 mg/mL (10,000 ppm)
Rituximab, 10 mg/mL (10,000 ppm)
Sorafenib Tosylate, 200 mg/mL (200,000 ppm)
Tamoxifen, 2 mg/mL (2,000 ppm)
Thiotepa, 10 mg/mL (10,000 ppm)
Topotecan HCL, 1 mg/mL (1,000 ppm)
Vinblastine Sulfate, 1 mg/mL (1,000 ppm)
Vinorelbine, 10 mg/mL (10,000 ppm)

Caution:
The following chemotherapy drugs and concentration showed breakthrough detected in less than 480 minutes:

Cytarabine (Cytosine), 100 mg/ml (100,000 ppm)	60 minutes
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	<30 minutes
Fludarabine, 25 mg/ml (25,000 ppm)	120 minutes
lfosfamide, 50 mg/ml (50,000 ppm)	30 minutes
lrinotecan HCI, 20 mg/ml (20,000 ppm)	240 minutes
Paclitaxel, 6 mg/ml (6,000 ppm)	120 minutes
Vincristine sulfate, 1 mg/ml (1,000 ppm)	<30 minutes

Per ASTM F3267-22, the following chemotherapy drugs had the following breakthrough at the Standard Breakthrough Rate of 0.1µg/cm^2/minute

Chemotherapy Drugs	Breakthrough Detection Time (min)	Cumulative Permeation (µg/cm^2)		
		30 min	60 min	240 min
Cyclophosphamide, 20 mg/mL (20,000 ppm)	120 minutes	0.00	0.00	516.00
Cytarabine HCl (Cytosine), 100 mg/mL (100,000 ppm)	60 minutes	0.26	0.46	68.35
Fludarabine, 25 mg/mL (25,000 ppm)	120 minutes	0.08	0.27	7.28

Irinotecan HCL, 20 mg/mL (20,000 ppm)	240 minutes	0.03	0.10	0.30
Paclitaxel (Taxol), 6 mg/mL (6,000 ppm)	120 minutes	0.00	0.00	1.64

The following hazardous drugs (opioids) and concentration had NO breakthrough detected within 480 minutes:

Fentanyl Citrate Injection, 100 mcg/2 ml
Fentanyl Citrate Injection / Simulated Gastric Acid Fluid Mix, 50/50 solution

Comparison of Technological Characteristics

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs.	Copioumed Chemotherapy Isolation Gown	Different
Intended Use/ Indication for Use	HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs and HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs are non-sterile, disposable, single-use AAMI PB70 Level 2 Procedure Gown worn by healthcare workers for minimal to low fluid contact situations involving water, blood, bodily fluids, or other fluids for general infection control and/or staff protection. Also, can be worn by healthcare workers during the administration of chemotherapy drugs to patients. Both the HALYARD* CHEMO360* Procedure Gown Tested for Use with Chemotherapy Drugs and the HALYARD* Procedure Gown Tested for Use with Chemotherapy Drugs were evaluated for resistance to permeation by selected chemotherapy drugs in accordance with ASTM F3267, *Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy Drugs*, using ASTM F739, *Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact*. The gowns meet the requirements for Part A: Selective Protection under ASTM F3267 based on the chemotherapy drug permeation testing conducted. Chemotherapy drug permeation resistance was reported as the average standardized breakthrough time over a 480-minute test period: Arsenic Trioxide (Trisenox), 1 mg/mL (1,000 ppm) Azacytidine (Vidaza), 25 mg/mL (25,000 ppm) Bendamustine HCl, 25 mg/mL (25,000 ppm) Bleomycin Sulfate, 15 mg/mL (15,000 ppm) Bortezomib, 1 mg/mL (1,000 ppm) Busulfan, 6 mg/mL (6,000 ppm)	Copioumed Chemotherapy Isolation Gown is intended to be worn by healthcare personnel to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate. Copioumed Chemotherapy Isolation Gown is non-sterile and for single use only. Copioumed Chemotherapy Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). Copioumed Chemotherapy Isolation Gown is a disposable device intended to protect health care personal from exposure to chemotherapy drugs during preparation, handling, and administration. The Copioumed Chemotherapy Isolation Gown has been evaluated for resistance to permeation of various chemotherapy drugs	Similar

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
	Carboplatin, 10 mg/mL (10,000 ppm) Car lzomib, 2 mg/mL (2,000 ppm) Carmustine, 3.3 mg/mL (3,300 ppm) Cladribine, 1 mg/mL (1,000 ppm) Cyclosporin A, 100 mg/mL (100,000 ppm) Cytovene (Ganciclovir), 10 mg/mL (10,000 ppm) Dacarbazine (DTIC), 10 mg/mL (10,000 ppm) Dactinomycin, 0.5 mg/mL (500 ppm) Daunorubicin HCl, 5 mg/mL (5,000 ppm) Decitabine, 5 mg/mL (5,000 ppm) Docetaxel, 10 mg/mL (10,000 ppm) Doxorubicin HCl, 2 mg/mL (2,000 ppm) Epirubicin HCl (Ellence), 2 mg/mL (2,000 ppm) Eribulin Mesylate, 0.5 mg/mL (500 ppm) Fluorouracil (Adrucil), 50 mg/mL (50,000 ppm) Gemcitabine HCL, 38 mg/mL (38,000 ppm) Idarubicin HCL, 1 mg/mL (1,000 ppm) Lenvatinib, 20 mg/mL (20,000 ppm) Leuprolide acetate salt, 5 mg/mL (5,000 ppm) Mechlorethamine HCl, 1 mg/mL (1,000 ppm) Melphalan HCl, 5 mg/mL (5,000 ppm) Methotrexate, 25 mg/mL (25,000 ppm) Mitomycin C, 0.5 mg/mL (500 ppm) Mitoxantrone HCl, 2 mg/mL (2,000 ppm) Oxaliplatin, 5 mg/mL (5,000 ppm) Pemetrexed, 25 mg/mL (25,000 ppm) Raltitrexed, 0.5 mg/mL (500 ppm) Retrovir, 10 mg/mL (10,000 ppm) Rituximab, 10 mg/mL (10,000 ppm) Sorafenib Tosylate, 200 mg/mL (200,000 ppm) Tamoxifen, 2 mg/mL (2,000 ppm) Thiotepa, 10 mg/mL (10,000 ppm) Topotecan HCL, 1 mg/mL (1,000 ppm) Vinblastine Sulfate, 1 mg/mL (1,000 ppm)	per ASTM F739-20 "Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact." Chemotherapy drug permeation resistance, average standardized breakthrough time in minutes.*: Carmustine [3.3 mg/ml] >480 Cisplatin [1.0 mg/ml] >480 Cyclophosphamide [20 mg/ml] >480 Cytarabine Hydrochloride [100 mg/ml] >480 Dacarbazine [10 mg/ml] >480 Daunorubicin Hydrochloride [5 mg/ml] >480 Doxorubicin Hydrochloride [2 mg/ml] > 480 Etoposide [20 mg/ml] >480 Fluorouracil [50 mg/ml] >480 Ifosfamide [50 mg/ml] > 480 Methotrexate [25 mg/ml] >480 Mitomycin C [0.5 mg/ml] >480 Mitoxantrone [2.0 mg/ml] >480 Paclitaxel [6 mg/ml] >480 Thiotepa [10 mg/ml] >480 Vincristine Sulfate [1 mg/ml] >480 *No permeation was detected at either the minimum detectable permeation or 0.1 $\mu g/cm^2/min$	

<table>
<tr><th>Device Characteristic</th><th>Proposed Device</th><th>Predicate Device</th><th>Comparison Analysis</th></tr>
<tr><td></td><td>
Vinorelbine, 10 mg/mL (10,000 ppm)

Caution:
The following chemotherapy drugs and concentration showed breakthrough detected in less than 480 minutes:
Cytarabine (Cytosine), 100 mg/ml (100,000 ppm) 60 minutes
Etoposide (Toposar), 20 mg/ml (20,000 ppm) <30 minutes
Fludarabine, 25 mg/ml (25,000 ppm) 120 minutes
lfosfamide, 50 mg/ml (50,000 ppm) 30 minutes
lrinotecan HCI, 20 mg/ml (20,000 ppm) 240 minutes
Paclitaxel, 6 mg/ml (6,000 ppm) 120 minutes
Vincristine sulfate, 1 mg/ml (1,000 ppm) <30 minutes

Per ASTM F3267-22, the following chemotherapy drugs had the following breakthrough at the Standard Breakthrough Rate of 0.1µg/cm^2/minute

<table>
<tr><th rowspan="2">Chemotherapy Drugs</th><th rowspan="2">Breakthrough Detection Time (min)</th><th colspan="3">Cumulative Permeation (µg/cm^2)</th></tr>
<tr><th>30 min</th><th>60 min</th><th>240 min</th></tr>
<tr><td>Cyclophosphamide, 20 mg/mL (20,000 ppm)</td><td>120 minutes</td><td>0.00</td><td>0.00</td><td>516.00</td></tr>
<tr><td>Cytarabine HCl (Cytosine), 100 mg/mL (100,000 ppm)</td><td>60 minutes</td><td>0.26</td><td>0.46</td><td>68.35</td></tr>
<tr><td>Fludarabine, 25 mg/mL (25,000 ppm)</td><td>120 minutes</td><td>0.08</td><td>0.27</td><td>7.28</td></tr>
<tr><td>Irinotecan HCL, 20 mg/mL (20,000 ppm)</td><td>240 minutes</td><td>0.03</td><td>0.10</td><td>0.30</td></tr>
<tr><td>Paclitaxel (Taxol), 6 mg/mL (6,000 ppm)</td><td>120 minutes</td><td>0.00</td><td>0.00</td><td>1.64</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
	The following hazardous drugs (opioids) and concentration had NO breakthrough detected within 480 minutes: Fentanyl Citrate Injection, 100 mcg/2 ml Fentanyl Citrate Injection / Simulated Gastric Acid Fluid Mix, 50/50 solution		
Color	Blue	Blue	Same
Design Features	HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs is a full back gown with a neck tape closure, front tie, and knit cuffs. HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs is an open back, over the head gown with knit cuffs.	Knit cuff in three style(model) Tie neck closure, Velcro neck closure and Sticker neck closure	Similar
Sizes	Large, XX-Large	Large, X-Large	Similar
Materials	1.02-1.42 osy Polypropylene Gown laminated with polypropylene-polyethylene film.	Polypropylene Gown laminated with polyethylene	Similar
Performance per AAMI PB70	AAMI Level 2	AAMI Level 3	Different [1]
Resistance to permeation of chemotherapy drugs testing	HALYARD* CHEMO360* Procedure Gown Tested for Use with Chemotherapy Drugs and the HALYARD* Procedure Gown Tested for Use with Chemotherapy Drugs were evaluated for resistance to permeation by selected chemotherapy drugs in accordance with ASTM F3267, *Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy Drugs*, using ASTM F739, *Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact*. The gowns meet the requirements for Part A: Selective Protection under ASTM F3267 based on the chemotherapy drug permeation testing conducted**.** Chemotherapy drug permeation resistance was reported as the average standardized breakthrough time over a 480-minute test period: Arsenic Trioxide (Trisenox), 1 mg/mL (1,000 ppm) Azacytidine (Vidaza), 25 mg/mL (25,000 ppm) Bendamustine HCl, 25 mg/mL (25,000 ppm) Bleomycin Sulfate, 15 mg/mL (15,000 ppm) Bortezomib, 1 mg/mL (1,000 ppm) Busulfan, 6 mg/mL (6,000 ppm) Carboplatin, 10 mg/mL (10,000 ppm)	ASTM F739-20 Results showed no average Standardized breakthrough for up to 480 minutes for claimed 16 drugs. Chemotherapy drug permeation resistance, average standardized breakthrough time in minutes.*: Carmustine [3.3 mg/ml] >480 Cisplatin [1.0 mg/ml] >480 Cyclophosphamide [20 mg/ml]>480 Cytarabine Hydrochloride [100 mg/ml] >480 Dacarbazine [10 mg/ml] >480 Daunorubicin Hydrochloride [5 mg/ml] >480 Doxorubicin Hydrochloride [2 mg/ml] > 480	Similar [2]

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
	Car lzomib, 2 mg/mL (2,000 ppm) Carmustine, 3.3 mg/mL (3,300 ppm) Cladribine, 1 mg/mL (1,000 ppm) Cyclosporin A, 100 mg/mL (100,000 ppm) Cytovene (Ganciclovir), 10 mg/mL (10,000 ppm) Dacarbazine (DTIC), 10 mg/mL (10,000 ppm) Dactinomycin, 0.5 mg/mL (500 ppm) Daunorubicin HCl, 5 mg/mL (5,000 ppm) Decitabine, 5 mg/mL (5,000 ppm) Docetaxel, 10 mg/mL (10,000 ppm) Doxorubicin HCl, 2 mg/mL (2,000 ppm) Epirubicin HCl (Ellence), 2 mg/mL (2,000 ppm) Eribulin Mesylate, 0.5 mg/mL (500 ppm) Fluorouracil (Adrucil), 50 mg/mL (50,000 ppm) Gemcitabine HCL, 38 mg/mL (38,000 ppm) Idarubicin HCL, 1 mg/mL (1,000 ppm) Lenvatinib, 20 mg/mL (20,000 ppm) Leuprolide acetate salt, 5 mg/mL (5,000 ppm) Mechlorethamine HCl, 1 mg/mL (1,000 ppm) Melphalan HCl, 5 mg/mL (5,000 ppm) Methotrexate, 25 mg/mL (25,000 ppm) Mitomycin C, 0.5 mg/mL (500 ppm) Mitoxantrone HCl, 2 mg/mL (2,000 ppm) Oxaliplatin, 5 mg/mL (5,000 ppm) Pemetrexed, 25 mg/mL (25,000 ppm) Raltitrexed, 0.5 mg/mL (500 ppm) Retrovir, 10 mg/mL (10,000 ppm) Rituximab, 10 mg/mL (10,000 ppm) Sorafenib Tosylate, 200 mg/mL (200,000 ppm) Tamoxifen, 2 mg/mL (2,000 ppm) Thiotepa, 10 mg/mL (10,000 ppm) Topotecan HCL, 1 mg/mL (1,000 ppm) Vinblastine Sulfate, 1 mg/mL (1,000 ppm) Vinorelbine, 10 mg/mL (10,000 ppm)	Etoposide [20 mg/ml] >480 Fluorouracil [50 mg/ml] >480 Ifosfamide [50 mg/ml] > 480 Methotrexate [25 mg/ml] >480 Mitomycin C [0.5 mg/ml] >480 Mitoxantrone [2.0 mg/ml] >480 Paclitaxel [6 mg/ml] >480 Thiotepa [10 mg/ml] >480 Vincristine Sulfate [1 mg/ml]>480 *No permeation was detected at either the minimum detectable permeation or 0.1 µg/cm2/min	

<table>
<tr><th>Device Characteristic</th><th>Proposed Device</th><th>Predicate Device</th><th>Comparison Analysis</th></tr>
<tr><td></td><td>
Caution:
The following chemotherapy drugs and concentration showed breakthrough detected in less than 480 minutes:
Cytarabine (Cytosine), 100 mg/ml (100,000 ppm) 60 minutes
Etoposide (Toposar), 20 mg/ml (20,000 ppm) <30 minutes
Fludarabine, 25 mg/ml (25,000 ppm) 120 minutes
lfosfamide, 50 mg/ml (50,000 ppm) 30 minutes
lrinotecan HCI, 20 mg/ml (20,000 ppm) 240 minutes
Paclitaxel, 6 mg/ml (6,000 ppm) 120 minutes
Vincristine sulfate, 1 mg/ml (1,000 ppm) <30 minutes

Per ASTM F3267-22, the following chemotherapy drugs had the following breakthrough at the Standard Breakthrough Rate of 0.1µg/cm^2/minute

<table>
<tr><th rowspan="2">Chemotherapy Drugs</th><th rowspan="2">Breakthrough Detection Time (min)</th><th colspan="3">Cumulative Permeation (µg/cm^2)</th></tr>
<tr><th>30 min</th><th>60 min</th><th>240 min</th></tr>
<tr><td>Cyclophosphamide, 20 mg/mL (20,000 ppm)</td><td>120 minutes</td><td>0.00</td><td>0.00</td><td>516.00</td></tr>
<tr><td>Cytarabine HCl (Cytosine), 100 mg/mL (100,000 ppm)</td><td>60 minutes</td><td>0.26</td><td>0.46</td><td>68.35</td></tr>
<tr><th rowspan="2">Chemotherapy Drugs</th><th rowspan="2">Breakthrough Detection Time (min)</th><th colspan="3">Cumulative Permeation (µg/cm^2)</th></tr>
<tr><th>30 min</th><th>60 min</th><th>240 min</th></tr>
<tr><td>Fludarabine, 25 mg/mL (25,000 ppm)</td><td>120 minutes</td><td>0.08</td><td>0.27</td><td>7.28</td></tr>
<tr><td>Irinotecan HCL, 20 mg/mL (20,000 ppm)</td><td>240 minutes</td><td>0.03</td><td>0.10</td><td>0.30</td></tr>
<tr><td>Paclitaxel (Taxol), 6 mg/mL (6,000 ppm)</td><td>120 minutes</td><td>0.00</td><td>0.00</td><td>1.64</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
	The following hazardous drugs (opioids) and concentration had NO breakthrough detected within 480 minutes: Fentanyl Citrate Injection, 100 mcg/2 ml Fentanyl Citrate Injection / Simulated Gastric Acid Fluid Mix, 50/50 solution		
Biocompatibility	Under the test conditions, the subject device was shown to be non- cytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10	Under the test conditions, the subject device was shown to be non- cytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10	Same
Flammability	Meets requirements of Flame Resistant CPSC 16 CFR 1610 Class 1	Meets requirements of Flame Resistant CPSC 16 CFR 1610 Class 1	Same
Tensile Strength	Meets the requirement of ASTM D5034-9	Meets the requirement of ASTM D5034-9	Same
Tear Resistance	Meets the requirement of ASTM D5587-15	Meets the requirement of ASTM D5587-15	Same
Seam Strength	Meets the requirement of ASTM 1683-17	Meets the requirement of ASTM 1683-17	Same

Different[1] While the proposed device and the predicate device differ in AAMI levels of protection, the predicate device was selected for the purpose of demonstrating evaluation of resistance to permeation against various chemotherapy drugs. The difference in the AAMI protection level is addressed through labeling.

Similar[2] The predicate device was selected solely to demonstrate evaluation for resistance to permeation by various chemotherapy drugs. Both the proposed device and the predicate device were tested for resistance to permeation of chemotherapy drugs in accordance with the standard ASTM F739, Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact. The proposed device was evaluated against a broader range of chemotherapy drugs than the predicate device. All chemotherapy drugs tested for the proposed device are clearly identified in the product labeling

Summary of Non-Clinical Testing

The subject device was evaluated through applicable non-clinical testing, and the results support the safety and performance of the device for its intended use.

Standard	Name	Acceptance Criteria	Result
ISO 10993-5	Tests for In Vitro Cytotoxicity	Non-Cytotoxicity	Pass
ISO 10993-10	Tests for Skin Irritation and Sensitization	Non-Irritation and Non-Sensitizing	Pass
AATCC 42-17	Water Resistance	AATCC 42 ≤ 1.0g	Pass
AATCC 127-18	Hydrostatic Pressure	AATCC 127 ≥ 50 cm H_2O	Pass
ASTM D5034-09	Breaking Strength and Elongation of Textile Fabrics (Grab Test)	≥ 30N	Pass
ASTM D5587-15	Tearing Strength of Fabrics by Trapezoid Procedure	≥ 10N	Pass
ASTM D1683	Seam strength	≥ 30N	Pass
16 CFR 1610	Flammability of Clothing Textiles	Class 1 (Normal flammability)	Pass
ANSI AAMI PB70:2022	Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Healthcare Facilities	Level 2	Pass
ASTM F739:2020	Permeation of Liquids and Gasses Through Protective Clothing	No permeation above detection limit during test period **or** breakthrough time ≥ specified time	Pass

Summary of Clinical Testing

No clinical testing was conducted for the subject device. Clinical testing was not considered necessary to support the safety and effectiveness of the device, as the relevant safety and performance characteristics can be adequately demonstrated through non-clinical testing

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device, the HALYARD* CHEMO360* Procedure Gown Tested for use with Chemotherapy Drugs and HALYARD* Procedure Gown Tested for use with Chemotherapy Drugs, is as safe, as effective, and performs as well as or better than the legally marketed predicate device in K230135, with respects to resistance to permeation of chemotherapy drugs and Fentanyl Citrate.