



September 22, 2020

O&M Halyard, Inc.
Steven Dowdley
Associate Director of Regulatory Affairs
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K200843

Trade/Device Name: Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Glove Tested
with Chemotherapy Drugs

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-Powdered Patient Examination Glove

Regulatory Class: Class I, reserved

Product Code: LZA, LZC, QDO

Dated: August 17, 2020

Received: August 21, 2020

Dear Steven Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K200843

Device Name

Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

Indications for Use (Describe)

Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs are disposable device intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with the following chemotherapy drugs and Fentanyl Citrate as per ASTM-D6978-05:

Azacitidine (Vidaza) (25 mg/ml) No breakthrough up to 240 minutes
Bendamustine (5 mg/ml) No breakthrough up to 240 minutes
Bleomycin sulfate (15 mg/ml) No breakthrough up to 240 minutes
Bortezomib (6 mg/ml) No breakthrough up to 240 minutes
Busulfan (6 mg/ml) No breakthrough up to 240 minutes
Capecitabine (26 mg/ml) No breakthrough up to 240 minutes
Carboplatin (10 mg/ml) No breakthrough up to 240 minutes
Carfilzomib (2 mg/ml) No breakthrough up to 240 minutes
Carmustine (3.3 mg/ml) permeation occurred at 59.0 minutes
Cetuximab (Erbix) (2 mg/ml) No breakthrough up to 240 minutes
Chloroquine (50 mg/ml) No breakthrough up to 240 minutes
Cisplatin (1 mg/ml) No breakthrough up to 240 minutes
Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes
Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes
Cyclosporine A (100 mg/ml) No breakthrough up to 240 minutes
Cytarabine HCL (100 mg/ml) No breakthrough up to 240 minutes
Cytovene (10 mg/ml) No breakthrough up to 240 minutes
Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes
Dactinomycin (0.5 mg/ml) No breakthrough up to 240 minutes
Daunorubicin HCL (5 mg/ml) No breakthrough up to 240 minutes
Decitabine (5 mg/ml) No breakthrough up to 240 minutes
Docetaxel (10 mg/ml) No breakthrough up to 240 minutes
Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes
Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes
Etoposide (20 mg/ml) No breakthrough up to 240 minutes
Fludarabine (25 mg/ml) No breakthrough up to 240 minutes
5-Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes
Fulvestrant (50 mg/ml) No breakthrough up to 240 minutes
Gemcitabine (38 mg/ml) No breakthrough up to 240 minutes
Idarubicin (1 mg/ml) No breakthrough up to 240 minutes
Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes
Irinotecan (20 mg/ml) No breakthrough up to 240 minutes
Leuprolide acetate salt (5mg/ml) No breakthrough up to 240 minutes
Methotrexate (25 mg/ml) No breakthrough up to 240 minutes
Mitomycin-C (0.5 mg/ml) No breakthrough up to 240 minutes

List of chemotherapy drugs continues on next page

K200843: Continuation of the list of chemotherapy drugs from previous page. These gloves were tested for use with the following chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05:

Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes
Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes
Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes
Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes
Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes
Retrovir (10 mg/ml) No breakthrough up to 240 minutes
Rituximab (10 mg/ml) No breakthrough up to 240 minutes
Temsirrolimus (25 mg/ml) No breakthrough up to 240 minutes
ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes
Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes
Triclosan (1 mg/ml) No breakthrough up to 240 minutes
Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes
Vinblastine (1 mg/ml) No breakthrough up to 240 minutes
Vincristine Sulfate (1 mg/ml) No breakthrough up to 240 minutes
Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes
Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes

Fentanyl Citrate Injection, (100mcg /2mL). No breakthrough up to 240 minutes

CAUTION: The following chemotherapy drugs and concentration showed breakthrough detected in less than 60 minutes:
Carmustine (BCNU): 59 minutes.

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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K200843 - Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

510(k) Summary

Date Summary was Prepared	September 19, 2020
510(k) Submitter	O & M Halyard, Inc. 5405 Windward Parkway Alpharetta, GA 30004
Primary Contact for this 510(k) Submission	Steven Dowdley, RAC Tel: 678-451-8062 Email: steven.dowdley@hyh.com
Device Trade Name	Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs
Device Common Name	Medical Exam Gloves
Device Product Code and Classification Name	LZC Class I, 21 CFR §880.6250 Patient Examination Glove LZC Class I, 21 CFR §880.6250 Patient Examination Glove, Specialty OQD Class I, 21 CFR §880.6250 Fentanyl and other opioid protection glove
Predicate Device	Halyard Pink Underguard Zero Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs cleared under K183132
Subject Device Description	<p>The Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs are disposable, pink-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, sterile patient examination gloves.</p> <p>The device follows consensus standards:</p> <ul style="list-style-type: none"> • ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves • ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications • ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves • ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs • ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for Systemic Toxicity • ISO 10993-10: 2010: Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization
Indications for Use for the Halyard Pink Underguard Zero, Sterile Powder-Free Exam Glove Tested with Chemotherapy	The Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with the following

K200843 - Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

<p>Drugs</p>	<p>chemotherapy drugs and Fentanyl Citrate as per ASTM -D6978-05.:</p> <p>Azacitidine (Vidaza) (25 mg/ml) No breakthrough up to 240 minutes Bendamustine (5 mg/ml) No breakthrough up to 240 minutes Bleomycin sulfate (15 mg/ml) No breakthrough up to 240 minutes Bortezomib (6 mg/ml) No breakthrough up to 240 minutes Busulfan (6 mg/ml) No breakthrough up to 240 minutes Capecitabine (26 mg/ml) No breakthrough up to 240 minutes Carboplatin (10 mg/ml) No breakthrough up to 240 minutes Carfilzomib (2 mg/ml) No breakthrough up to 240 minutes Carmustine (3.3 mg/ml) permeation occurred at 59.0 minutes Cetuximab (Erbix) (2 mg/ml) No breakthrough up to 240 minutes Chloroquine (50 mg/ml) No breakthrough up to 240 minutes Cisplatin (1 mg/ml) No breakthrough up to 240 minutes Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes Cyclosporine A (100 mg/ml) No breakthrough up to 240 minutes Cytarabine HCL (100 mg/ml) No breakthrough up to 240 minutes Cytovene (10 mg/ml) No breakthrough up to 240 minutes Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes Dactinomycin (0.5 mg/ml) No breakthrough up to 240 minutes Daunorubicin HCL (5 mg/ml) No breakthrough up to 240 minutes Decitabine (5 mg/ml) No breakthrough up to 240 minutes Docetaxel (10 mg/ml) No breakthrough up to 240 minutes Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes Etoposide (20 mg/ml) No breakthrough up to 240 minutes Fludarabine (25 mg/ml) No breakthrough up to 240 minutes 5-Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes Fulvestrant (50 mg/ml) No breakthrough up to 240 minutes Gemcitabine (38 mg/ml) No breakthrough up to 240 minutes Idarubicin (1 mg/ml) No breakthrough up to 240 minutes Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes Irinotecan (20 mg/ml) No breakthrough up to 240 minutes Leuprolide acetate salt (5mg/ml) No breakthrough up to 240 minutes Methotrexate (25 mg/ml) No breakthrough up to 240 minutes Methotrexate (25 mg/ml) No breakthrough up to 240 minutes Mitomycin-C (0.5 mg/ml) No breakthrough up to 240 minutes Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes Retrovir (10 mg/ml) No breakthrough up to 240 minutes Rituximab (10 mg/ml) No breakthrough up to 240 minutes Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes Triclosan (1 mg/ml) No breakthrough up to 240 minutes Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes Vinblastine (1 mg/ml) No breakthrough up to 240 minutes Vincristine Sulfate (1 mg/ml) No breakthrough up to 240 minutes Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes</p> <p>Fentanyl Citrate (100mcg/2ml) No breakthrough up to 240 minutes.</p> <p>CAUTION: The following chemotherapy drugs and concentration showed breakthrough detected in less than 60 minutes: Carmustine (BCNU): 59 minutes.</p>
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K200843 - Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

Summary of comparison of technological characteristics		The subject device and the predicate device are both sterile, powder-free nitrile exam gloves tested for resistance to permeation by chemotherapy drugs.
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Technological Characteristics Comparison Table			
	Subject Device	Predicate Device K183132	Comparison
FDA Product Code	LZA, LZC, QDO	LZA, LZC	Same
FDA Classification	Class I	Class I	Same
Regulation Number	880.6250	880.6250	Same
Common Name	Medical Exam Glove	Medical Exam Glove	Same
Device Trade Name	Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs	Halyard Pink Underguard Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs	Similar
Intended Use	Halyard Pink Underguard Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs are disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs listed on the label.	The Halyard Pink Underguard Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs listed on the label.	Same
Technological Characteristics	The glove is a colored, nitrile, powder-free, textured fingertip, ambidextrous, patient examination glove.	The glove is a colored, nitrile, powder-free, textured fingertip, ambidextrous, patient examination glove.	Same
Sizes of gloves	XS, S, M, L, XL (Sterile)	XS, S, M, L, XL	Different
Texture	Textured fingertips (Sterile)	Textured fingertips	Different

K200843 - Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

Sterility	Sterile.	Non Sterile	Different
Biocompatibility	Based ISO 10993 Biological evaluation of Medical devices – Test for Systemic Injection, the test article was considered non-toxic. Meets the acceptance criteria.	Based ISO 10993 Biological evaluation of Medical devices – Test for Systemic Injection, the test article was considered non-toxic. Meets the acceptance criteria.	Similar
	Based on ISO 10993- Biological evaluation of Medical Devices – Test for Skin Irritation, the device extracts were not found to cause a systemic response in the animal model. Meets the acceptance criteria.	Based on ISO 10993- Biological evaluation of Medical Devices – Test for Skin Irritation, the device extracts were not found to cause a systemic response in the animal model. Meets the acceptance criteria.	
	Based on ISO 10993- Biological evaluation of Medical Device Dermal Sensitization- ISO Kligman Maximization Test - NaCl and CSO extracts. The test article were classified as a non-sensitizer. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.	Based on ISO 10993- Biological evaluation of Medical Device Dermal Sensitization- ISO Kligman Maximization Test - NaCl and CSO extracts. The test article were classified as a non-sensitizer. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.	

Performance Data for Chemotherapy Drugs			
Standard	Results Subject Device (sterile)	Results Predicate Device K183132	Remarks
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	<p>Azacitidine (Vidaza) (25 mg/ml) No breakthrough up to 240 minutes</p> <p>Bendamustine (5 mg/ml) No breakthrough up to 240 minutes</p> <p>Bleomycin sulfate (15 mg/ml) No breakthrough up to 240 minutes</p> <p>Bortezomib (6 mg/ml) No breakthrough up to 240 minutes</p> <p>Busulfan (6 mg/ml) No breakthrough up to 240 minutes</p> <p>Capecitabine (26 mg/ml) No breakthrough up to 240 minutes</p> <p>Carboplatin (10 mg/ml) No breakthrough up to 240 minutes</p> <p>Carfilzomib (2 mg/ml) No breakthrough up to 240 minutes</p> <p>Carmustine (3.3 mg/ml) permeation occurred at 59.0 minutes</p>	<p>Arsenic Trioxide (1 mg/ml) No breakthrough up to 240 minutes</p> <p>Azacitidine (Vidaza) (25 mg/ml) No breakthrough up to 240 minutes</p> <p>Bendamustine (5 mg/ml) No breakthrough up to 240 minutes</p> <p>Bortezomib (Velcade) (1 mg/ml) No breakthrough up to 240 minutes</p> <p>Bleomycin sulfate (15 mg/ml) No breakthrough up to 240 minutes</p> <p>Busulfan (6 mg/ml) No breakthrough up to 240 minutes</p> <p>Carboplatin (10 mg/ml) No breakthrough up to 240 minutes</p> <p>Carfilzomib (2 mg/ml) No breakthrough up to 240 minutes</p> <p>Carmustine (3.3 mg/ml) permeation occurred at 54.7 minutes</p>	Similar

K200843 - Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

Cetuximab (Erbix) (2 mg/ml) No breakthrough up to 240 minutes	Cetuximab (Erbix) (2 mg/ml) No breakthrough up to 240 minutes
Chloroquine (50 mg/ml) No breakthrough up to 240 minutes	Cisplatin (1 mg/ml) No breakthrough up to 240 minutes
Cisplatin (1 mg/ml) No breakthrough up to 240 minutes	Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes
Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes	Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes
Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes	Cytarabine HCL (100 mg/ml) No breakthrough up to 240 minutes
Cyclosporine A (100 mg/ml) No breakthrough up to 240 minutes	Cytovene (10 mg/ml) No breakthrough up to 240 minutes
Cytarabine HCL (100 mg/ml) No breakthrough up to 240 minutes	Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes
Cytovene (10 mg/ml) No breakthrough up to 240 minutes	Daunorubicin HCL (5 mg/ml) No breakthrough up to 240 minutes
Dacarbazine (10 mg/ml) No breakthrough up to 240 minutes	Decitabine (5 mg/ml) No breakthrough up to 240 minutes
Dactinomycin (0.5 mg/ml) No breakthrough up to 240 minutes	Docetaxel (10 mg/ml) No breakthrough up to 240 minutes
Daunorubicin HCL (5 mg/ml) No breakthrough up to 240 minutes	Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes
Decitabine (5 mg/ml) No breakthrough up to 240 minutes	Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes
Docetaxel (10 mg/ml) No breakthrough up to 240 minutes	Etoposide (20 mg/ml) No breakthrough up to 240 minutes
Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes	Fludarabine (25 mg/ml) No breakthrough up to 240 minutes
Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes	Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes
Etoposide (20 mg/ml) No breakthrough up to 240 minutes	Fulvestrant (50 mg/ml) No breakthrough up to 240 minutes
Fludarabine (25 mg/ml) No breakthrough up to 240 minutes	Gemcitabine (38 mg/ml) No breakthrough up to 240 minutes
5-Fluorouracil (50 mg/ml) No breakthrough up to 240 minutes	Idarubicin (1 mg/ml) No breakthrough up to 240 minutes
Fulvestrant (50 mg/ml) No breakthrough up to 240 minutes	Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes
Gemcitabine (38 mg/ml) No breakthrough up to 240 minutes	Irinotecan (20 mg/ml) No breakthrough up to 240 minutes
Idarubicin (1 mg/ml) No breakthrough up to 240 minutes	Mechlorethamine HCL (1 mg/ml) No breakthrough up to 240 minutes
Ifosfamide (50 mg/ml) No breakthrough up to 240 minutes	Melphalan (5 mg/ml) No breakthrough up to 240 minutes
Irinotecan (20 mg/ml) No breakthrough up to 240 minutes	Methotrexate (25 mg/ml) No breakthrough up to 240 minutes

K200843 - Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

Leuprolide acetate salt (5mg/ml) No breakthrough up to 240 minutes	Mitomycin-C (0.5 mg/ml) No breakthrough up to 240 minutes
Mechlorethamine HCL (1 mg/ml) No breakthrough up to 240 minutes	Mitoxantrone (2 mg/ml) Nobreakthrough up to 240 minutes
Melphalan (5 mg/ml) No breakthrough up to 240 minutes	Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes
Methotrexate (25 mg/ml) No breakthrough up to 240 minutes	Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes
Mitomycin-C (0.5 mg/ml) No breakthrough up to 240 minutes	Paraplatin (10 mg/ml) No breakthrough up to 240 minutes
Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes	Pemetrexed (25 mg/ml) Nobreakthrough up to 240 minutes
Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes	Pertuzumab (30 mg/ml) Nobreakthrough up to 240 minutes
Paclitaxel (6 mg/ml) Nobreakthrough up to 240 minutes	Raltitrexed (0.5 mg/ml) Nobreakthrough up to 240 minutes
Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes	Retrovir (10 mg/ml) No breakthrough up to 240 minutes
Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes	Rituximab (10 mg/ml) No breakthrough up to 240 minutes
Retrovir (10 mg/ml) No breakthrough up to 240 minutes	Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes
Rituximab (10 mg/ml) Nobreakthrough up to 240 minutes	Trastuzumab (21 mg/ml) No breakthrough up to 240 minutes
Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes	ThioTEPA (10 mg/ml) No breakthrough up to 134.7 minutes
ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes	Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes
Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes	Triclosan (1 mg/ml) No breakthrough up to 240 minutes
Triclosan (1 mg/ml) No breakthrough up to 240 minutes	Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes
Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes	Vincristine Sulfate (1 mg/ml) No breakthrough up to 240 minutes
Vinblastine (1 mg/ml) Nobreakthrough up to 240 minutes	Vinblastine (1 mg/ml) No breakthrough up to 240 minutes
Vincristine Sulfate (1 mg/ml) No breakthrough up to 240 minutes	Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes
Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes	Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes
Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes	

K200843 - Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs

Performance Data for Chemotherapy Drugs			
Standard	Results Subject Device (sterile)	Results Predicate Device K183132	Remarks
ASTM D 6978	Fentanyl Citrate Injection, (100mcg /2mL). No breakthrough up to 240 minutes	No tested	Different

ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves	Testing of the subject device shows it meets the 2.5% AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard.	Testing of the subject device shows it meets the 2.5% AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard.	Same
ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves	Residual powder on the subject device is an average of 0.4 mg/glove within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free.	Residual powder on the subject device is an average of 0.4 mg/glove within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free.	Same
ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications	The physical dimensions of the subject device are within the limits of the standard and the physical properties of the subject device met the requirements for tensile strength before and after aging. The subject device also met the requirement for elongation before and after aging.	The physical dimensions of the subject device are within the limits of the standard and the physical properties of the subject device met the requirements for tensile strength before and after aging. The subject device also met the requirement for elongation before and after aging.	Same
ISO 10993 Biological evaluation of medical devices	Meets acceptance criteria	Meets acceptance criteria	Same
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs are as safe, as effective, and performs as well as or better than the legally marketed predicate device.		