



November 8, 2019

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

Re: K191230

Trade/Device Name: Halyard Sterling\* Nitrile Powder-Free Exam Gloves, Halyard Sterling SG\*  
Nitrile Sensi-Guard Powder-Free Exam Gloves

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-Powdered Patient Examination Glove

Regulatory Class: Class I, reserved

Product Code: LZC

Dated: July 19, 2019

Received: August 13, 2019

Dear Steve 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.  
Assistant Director for THT4B2  
Acting Assistant Director for THT4B1  
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)

K191230

Device Name

Halyard Sterling Nitrile Powder-Free Exam Gloves

Indications for Use (Describe)

The Halyard Sterling Nitrile Powder-Free Exam Gloves 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 chemotherapy drugs:

Arsenic Trioxide (1 mg/ml), No breakthrough up to 240 minutes  
Doxorubicin HCL (2 mg/ml), No breakthrough up to 240 minutes  
Paclitaxel (6 mg/ml), No breakthrough up to 240 minutes  
Azacitidine (Vidaza) (25 mg/ml), No breakthrough up to 240 minutes  
Epirubicin (Ellence) (2 mg/ml), No breakthrough up to 240 minutes  
Paraplatin (10 mg/ml), No breakthrough up to 240 minutes  
Bendamustine (5 mg/ml), No breakthrough up to 240 minutes  
Eribulin Mesylate (0.5 mg/ml), No breakthrough up to 240 minutes  
Pemetrexed (25 mg/ml), No breakthrough up to 240 minutes  
Bortezomib (Velcade) (1 mg/ml), No breakthrough up to 240 minutes  
Etoposide (20 mg/ml), No breakthrough up to 240 minutes  
Pertuzumab (30 mg/ml), No breakthrough up to 240 minutes  
Bleomycin sulfate (15 mg/ml), No breakthrough up to 240 minutes  
Fludarabine (25 mg/ml), No breakthrough up to 240 minutes  
Raltitrexed (0.5 mg/ml), No breakthrough up to 240 minutes  
Busulfan (6 mg/ml), No breakthrough up to 240 minutes  
Fluorouracil (50 mg/ml), No breakthrough up to 240 minutes,  
Retrovir (10 mg/ml) No breakthrough up to 240 minutes  
Carboplatin (10 mg/ml), No breakthrough up to 240 minutes  
Fulvestrant (50 mg/ml), No breakthrough up to 240 minutes  
Rituximab (10 mg/ml), No breakthrough up to 240 minutes  
Carfilzomib (2 mg/ml), No breakthrough up to 240 minutes  
Gemcitabine (38 mg/ml), No breakthrough up to 240 minutes  
Temsirolimus (25 mg/ml), No breakthrough up to 240 minutes  
Cetuximab (Erbix) (2 mg/ml), No breakthrough up to 240 minutes  
Idarubicin (1 mg/ml), No breakthrough up to 240 minutes  
Trastuzumab (21 mg/ml), No breakthrough up to 240 minutes  
Cisplatin (1 mg/ml), No breakthrough up to 240 minutes  
Ifosfamide (50 mg/ml), No breakthrough up to 240 minutes  
Topotecan HCL (1 mg/ml), No breakthrough up to 240 minutes  
Cyclophosphamide (20 mg/ml), No breakthrough up to 240 minutes  
Irinotecan (20 mg/ml), No breakthrough up to 240 minutes  
Triclosan (2 mg/ml), No breakthrough up to 240 minutes  
Cytarabine HCL (100 mg/ml), No breakthrough up to 240 minutes  
Mechlorethamine HCL (1 mg/ml), No breakthrough up to 240 minutes  
Trisonex (1 mg/ml), No breakthrough up to 240 minutes  
Cytovene (10 mg/ml), No breakthrough up to 240 minutes  
Melfalan (5 mg/ml), No breakthrough up to 240 minutes  
Vincristine Sulfate (1 mg/ml), No breakthrough up to 240 minutes

---

Dacarbazine (10 mg/ml), No breakthrough up to 240 minutes  
Methotrexate (25 mg/ml), No breakthrough up to 240 minutes,  
Vinblastine (1 mg/ml), No breakthrough up to 240 minutes  
Daunorubicin HCL (5 mg/ml), No breakthrough up to 240 minutes  
Mitomycin-C (0.5 mg/ml), No breakthrough up to 240 minutes  
Vinorelbine (10 mg/ml), No breakthrough up to 240 minutes  
Decitabine (5 mg/ml), No breakthrough up to 240 minutes  
Mitoxantrone (2 mg/ml), No breakthrough up to 240 minutes  
Zoledronic Acid (0.8 mg/ml), No breakthrough up to 240 minutes  
Docetaxel (10 mg/ml), No breakthrough up to 240 minutes  
Oxaliplatin (2 mg/ml), No breakthrough up to 240 minutes

ThioTEPA (10 mg/ml), breakthrough detected at 37.1 minutes  
Carmustine (3.3 mg/ml), breakthrough detected at 22.9 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.**

---

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

## Indications for Use

510(k) Number (if known)

K191230

Device Name

Halyard Sterling SG \* Nitrile Sensi-Guard Powder-Free Exam Gloves

Indications for Use (Describe)

The Halyard Sterling SG\* Nitrile Sensi-Guard Powder-Free Exam Gloves 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 chemotherapy drugs:

Arsenic Trioxide (1 mg/ml), No breakthrough up to 240 minutes  
Doxorubicin HCL (2 mg/ml), No breakthrough up to 240 minutes  
Paclitaxel (6 mg/ml), No breakthrough up to 240 minutes  
Azacitidine (Vidaza) (25 mg/ml), No breakthrough up to 240 minutes  
Epirubicin (Ellence) (2 mg/ml), No breakthrough up to 240 minutes  
Paraplatin (10 mg/ml), No breakthrough up to 240 minutes  
Bendamustine (5 mg/ml), No breakthrough up to 240 minutes  
Eribulin Mesylate (0.5 mg/ml), No breakthrough up to 240 minutes  
Pemetrexed (25 mg/ml), No breakthrough up to 240 minutes  
Bortezomib (Velcade) (1 mg/ml), No breakthrough up to 240 minutes  
Etoposide (20 mg/ml), No breakthrough up to 240 minutes  
Pertuzumab (30 mg/ml), No breakthrough up to 240 minutes  
Bleomycin sulfate (15 mg/ml), No breakthrough up to 240 minutes  
Fludarabine (25 mg/ml), No breakthrough up to 240 minutes  
Raltitrexed (0.5 mg/ml), No breakthrough up to 240 minutes  
Busulfan (6 mg/ml), No breakthrough up to 240 minutes  
Fluorouracil (50 mg/ml), No breakthrough up to 240 minutes  
Retrovir (10 mg/ml) No breakthrough up to 240 minutes  
Carboplatin (10 mg/ml), No breakthrough up to 240 minutes  
Fulvestrant (50 mg/ml), No breakthrough up to 240 minutes  
Rituximab (10 mg/ml), No breakthrough up to 240 minutes  
Carfilzomib (2 mg/ml), No breakthrough up to 240 minutes  
Gemcitabine (38 mg/ml), No breakthrough up to 240 minutes  
Temsirolimus (25 mg/ml), No breakthrough up to 240 minutes  
Cetuximab (Erbix) (2 mg/ml), No breakthrough up to 240 minutes  
Idarubicin (1 mg/ml), No breakthrough up to 240 minutes  
Trastuzumab (21 mg/ml), No breakthrough up to 240 minutes  
Cisplatin (1 mg/ml), No breakthrough up to 240 minutes  
Ifosfamide (50 mg/ml), No breakthrough up to 240 minutes  
Topotecan HCL (1 mg/ml), No breakthrough up to 240 minutes  
Cyclophosphamide (20 mg/ml), No breakthrough up to 240 minutes  
Irinotecan (20 mg/ml), No breakthrough up to 240 minutes  
Triclosan (2 mg/ml), No breakthrough up to 240 minutes  
Cytarabine HCL (100 mg/ml), No breakthrough up to 240 minutes  
Mechlorethamine HCL (1 mg/ml), No breakthrough up to 240 minutes  
Trisonex (1 mg/ml), No breakthrough up to 240 minutes  
Cytovene (10 mg/ml), No breakthrough up to 240 minutes  
Melfalan (5 mg/ml), No breakthrough up to 240 minutes  
Vincristine Sulfate (1 mg/ml), No breakthrough up to 240 minutes

---

Dacarbazine (10 mg/ml), No breakthrough up to 240 minutes  
Methotrexate (25 mg/ml), No breakthrough up to 240 minutes,  
Vinblastine (1 mg/ml), No breakthrough up to 240 minutes  
Daunorubicin HCL (5 mg/ml), No breakthrough up to 240 minutes  
Mitomycin-C (0.5 mg/ml), No breakthrough up to 240 minutes  
Vinorelbine (10 mg/ml), No breakthrough up to 240 minutes  
Decitabine (5 mg/ml), No breakthrough up to 240 minutes  
Mitoxantrone (2 mg/ml), No breakthrough up to 240 minutes  
Zoledronic Acid (0.8 mg/ml), No breakthrough up to 240 minutes  
Docetaxel (10 mg/ml), No breakthrough up to 240 minutes  
Oxaliplatin (2 mg/ml), No breakthrough up to 240 minutes

ThioTEPA (10 mg/ml), breakthrough detected at 23.9 minutes  
Carmustine (3.3 mg/ml), breakthrough detected at 14.8 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.**

---

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

**510(k) Summary**

<b>Date Summary was Prepared</b>	Nov 4, 2019
<b>510(k) Submitter</b>	Owens & Minor Halyard, Inc 9120 Lockwood Blvd Mechanicsville, VA 23116
<b>Primary Contact for this 510(k) Submission</b>	Steven Dowdley, RAC Tel: 678-451-8062 Email: <a href="mailto:steven.dowdley@hyh.com">steven.dowdley@hyh.com</a>
<b>Device Trade Name</b>	Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves and Halyard STERLING* Nitrile Powder-Free Exam Gloves
<b>Device Common Name</b>	Medical Exam Gloves
<b>Device Product Code and Classification Name</b>	LZC Class I, 21 CFR §880.6250 Patient Examination Glove
<b>Predicate Device</b>	K180646  Halyard Lavender Nitrile Powder-Free Exam Gloves
<b>Subject Device Description</b>	Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves and Halyard STERLING* Nitrile Powder-Free Exam Gloves tested for Use with Chemotherapy Drugs are disposable, grey-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves that are packed in a cardboard dispenser box.



<p><b>Indications for Use for Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves</b></p>	<p>The Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves 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 chemotherapy drugs:</p> <p>Arsenic Trioxide (1 mg/ml), No breakthrough up to 240 minutes  Doxorubicin HCL (2 mg/ml), No breakthrough up to 240 minutes  Paclitaxel (6 mg/ml), No breakthrough up to 240 minutes  Azacitidine (Vidaza) (25 mg/ml), No breakthrough up to 240 minutes  Epirubicin (Ellence) (2 mg/ml), No breakthrough up to 240 minutes  Paraplatin (10 mg/ml), No breakthrough up to 240 minutes  Bendamustine (5 mg/ml), No breakthrough up to 240 minutes  Eribulin Mesylate (0.5 mg/ml), No breakthrough up to 240 minutes  Pemetrexed (25 mg/ml), No breakthrough up to 240 minutes  Bortezomib (Velcade) (1 mg/ml), No breakthrough up to 240 minutes  Etoposide (20 mg/ml), No breakthrough up to 240 minutes  Pertuzumab (30 mg/ml), No breakthrough up to 240 minutes  Bleomycin sulfate (15 mg/ml), No breakthrough up to 240 minutes  Fludarabine (25 mg/ml), No breakthrough up to 240 minutes  Raltitrexed (0.5 mg/ml), No breakthrough up to 240 minutes  Busulfan (6 mg/ml), No breakthrough up to 240 minutes  Fluorouracil (50 mg/ml), No breakthrough up to 240 minutes, No breakthrough up to 240 minutes  Retrovir (10 mg/ml) No breakthrough up to 240 minutes  Carboplatin (10 mg/ml), No breakthrough up to 240 minutes  Fulvestrant (50 mg/ml), No breakthrough up to 240 minutes  Rituximab (10 mg/ml), No breakthrough up to 240 minutes  Carfilzomib (2 mg/ml), No breakthrough up to 240 minutes  Gemcitabine (38 mg/ml), No breakthrough up to 240 minutes  Temsirolimus (25 mg/ml), No breakthrough up to 240 minutes  Cetuximab (Erbix) (2 mg/ml), No breakthrough up to 240 minutes  Idarubicin (1 mg/ml), No breakthrough up to 240 minutes  Trastuzumab (21 mg/ml), No breakthrough up to 240 minutes  Cisplatin (1 mg/ml), No breakthrough up to 240 minutes  Ifosfamide (50 mg/ml), No breakthrough up to 240 minutes  Topotecan HCL (1 mg/ml), No breakthrough up to 240 minutes  Cyclophosphamide (20 mg/ml), No breakthrough up to 240 minutes  Irinotecan (20 mg/ml), No breakthrough up to 240 minutes  Triclosan (2 mg/ml), No breakthrough up to 240 minutes  Cytarabine HCL (100 mg/ml), No breakthrough up to 240 minutes  Mechlorethamine HCL (1 mg/ml), No breakthrough up to 240 minutes  Trisonex (1 mg/ml), No breakthrough up to 240 minutes  Cytovene (10 mg/ml), No breakthrough up to 240 minutes  Melphalan (5 mg/ml), No breakthrough up to 240 minutes  Vincristine Sulfate (1 mg/ml), No breakthrough up to 240 minutes  Dacarbazine (10 mg/ml), No breakthrough up to 240 minutes</p>
--	---



	<p>Methotrexate (25 mg/ml), No breakthrough up to 240 minutes, Vinblastine (1 mg/ml), No breakthrough up to 240 minutes Daunorubicin HCL (5 mg/ml), No breakthrough up to 240 minutes Mitomycin-C (0.5 mg/ml), No breakthrough up to 240 minutes Vinorelbine (10 mg/ml), No breakthrough up to 240 minutes Decitabine (5 mg/ml), No breakthrough up to 240 minutes Mitoxantrone (2 mg/ml), No breakthrough up to 240 minutes Zoledronic Acid (0.8 mg/ml), No breakthrough up to 240 minutes Docetaxel (10 mg/ml), No breakthrough up to 240 minutes Oxaliplatin (2 mg/ml), No breakthrough up to 240 minutes</p> <p>ThioTEPA (10 mg/ml), breakthrough detected at 23.9 minutes Carmustine (3.3 mg/ml), breakthrough detected at 14.8 minutes</p>
--	--

<p><b>Indications for Use for Halyard Sterling Nitrile Powder-Free Exam Gloves</b></p>	<p>The Halyard STERLING* Nitrile Powder-Free Exam Gloves Tested for Use 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 chemotherapy drugs:</p> <p>Arsenic Trioxide (1 mg/ml), No breakthrough up to 240 minutes  Doxorubicin HCL (2 mg/ml), No breakthrough up to 240 minutes  Paclitaxel (6 mg/ml), No breakthrough up to 240 minutes  Azacitidine (Vidaza) (25 mg/ml), No breakthrough up to 240 minutes  Epirubicin (Ellence) (2 mg/ml), No breakthrough up to 240 minutes  Paraplatin (10 mg/ml), No breakthrough up to 240 minutes  Bendamustine (5 mg/ml), No breakthrough up to 240 minutes  Eribulin Mesylate (0.5 mg/ml), No breakthrough up to 240 minutes  Pemetrexed (25 mg/ml), No breakthrough up to 240 minutes  Bortezomib (Velcade) (1 mg/ml), No breakthrough up to 240 minutes  Etoposide (20 mg/ml), No breakthrough up to 240 minutes  Pertuzumab (30 mg/ml), No breakthrough up to 240 minutes  Bleomycin sulfate (15 mg/ml), No breakthrough up to 240 minutes  Fludarabine (25 mg/ml), No breakthrough up to 240 minutes  Raltitrexed (0.5 mg/ml), No breakthrough up to 240 minutes  Busulfan (6 mg/ml), No breakthrough up to 240 minutes  Fluorouracil (50 mg/ml), No breakthrough up to 240 minutes  Retrovir (10 mg/ml) No breakthrough up to 240 minutes  Carboplatin (10 mg/ml), No breakthrough up to 240 minutes  Fulvestrant (50 mg/ml), No breakthrough up to 240 minutes  Rituximab (10 mg/ml), No breakthrough up to 240 minutes  Carfilzomib (2 mg/ml), No breakthrough up to 240 minutes  Gemcitabine (38 mg/ml), No breakthrough up to 240 minutes  Temsilimus (25 mg/ml), No breakthrough up to 240 minutes  Cetuximab (Erbix) (2 mg/ml), No breakthrough up to 240 minutes  Idarubicin (1 mg/ml), No breakthrough up to 240 minutes  Trastuzumab (21 mg/ml), No breakthrough up to 240 minutes  Cisplatin (1 mg/ml), No breakthrough up to 240 minutes  Ifosfamide (50 mg/ml), No breakthrough up to 240 minutes  Topotecan HCL (1 mg/ml), No breakthrough up to 240 minutes  Cyclophosphamide (20 mg/ml), No breakthrough up to 240 minutes  Irinotecan (20 mg/ml), No breakthrough up to 240 minutes  Triclosan (2 mg/ml), No breakthrough up to 240 minutes  Cytarabine HCL (100 mg/ml), No breakthrough up to 240 minutes  Mechlorethamine HCL (1 mg/ml), No breakthrough up to 240 minutes  Trisonex (1 mg/ml), No breakthrough up to 240 minutes  Cytovene (10 mg/ml), No breakthrough up to 240 minutes  Melphalan (5 mg/ml), No breakthrough up to 240 minutes  Vincristine Sulfate (1 mg/ml), No breakthrough up to 240 minutes  Dacarbazine (10 mg/ml), No breakthrough up to 240 minutes</p>
--	--

	<p>Methotrexate (25 mg/ml), No breakthrough up to 240 minutes,          Vinblastine (1 mg/ml), No breakthrough up to 240 minutes          Daunorubicin HCL (5 mg/ml), No breakthrough up to 240 minutes          Mitomycin-C (0.5 mg/ml), No breakthrough up to 240 minutes          Vinorelbine (10 mg/ml), No breakthrough up to 240 minutes          Decitabine (5 mg/ml), No breakthrough up to 240 minutes          Mitoxantrone (2 mg/ml), No breakthrough up to 240 minutes          Zoledronic Acid (0.8 mg/ml), No breakthrough up to 240 minutes          Docetaxel (10 mg/ml), No breakthrough up to 240 minutes          Oxaliplatin (2 mg/ml), No breakthrough up to 240 minutes</p> <p>ThioTEPA (10 mg/ml), breakthrough detected at 37.1 minutes          Carmustine (3.3 mg/ml), breakthrough detected at 22.9 minutes</p>
<b>Summary of comparison of technological characteristics</b>	Both the subject devices and the predicate devices are sterile, powder-free nitrile exam gloves tested for resistance to permeation by chemotherapy drugs.

<b>Technological Characteristics Table</b>				
	<b>Subject Device Halyard Sterling SG* Nitrile Sensi- Guard Powder- Free Exam Gloves</b>	<b>Subject Device Halyard Sterling Nitrile Powder- Free Exam Gloves</b>	<b>Predicate K180646</b>	<b>Comparison</b>
<b>FDA Product Code</b>	LZC	LZC	LZC	Same
<b>FDA Classification</b>	Class I	Class I	Class I	Same
<b>Regulation</b>	880.6250	880.6250	880.6250	Same
<b>Common Name</b>	Medical Exam	Medical Exam Glove	Medical Exam	Same
<b>Device Trade Name</b>	Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves	Halyard Sterling Nitrile Powder-Free Exam Gloves	Halyard Lavender Nitrile Powder-Free Exam Gloves	Similar
<b>Characteristics</b>	Grey- colored, 9.5 inch, nitrile, 0.08 mm thick at palm, powder-free, textured fingertips, ambidextrous, non-sterile patient examination glove	Grey- colored, 9.5 inch, nitrile, 0.08 mm thick at palm, powder-free, textured fingertips, ambidextrous, non-sterile patient examination glove	Lavender-colored, 9.5 inch, nitrile, 0.08 mm thick at palm, powder-free, textured fingertips, ambidextrous, non-sterile patient examination glove	Similar
<b>Sizes of gloves</b>	XS, S, M, L, XL	XS, S, M, L, XL	XS, S, M, L, XL	Same

<b>Texture</b>	Textured fingertips	Textured finger tips	Textured finger tips	Same
<b>Sterility</b>	Non-sterile	Non-sterile	Non-sterile	Same
<b>Summary of comparison of technological characteristics</b>	There are no different technological characteristics of the subject devices, (Halyard of technological Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves and Halyard STERLING* Nitrile Powder-Free Exam Gloves) compared to the predicate device. They are powder-free nonsterile nitrile exam gloves tested for resistance to permeation by chemotherapy drugs. The subject devices were tested for use with 52 drugs and the predicate device was tested for use with 12 drugs. The color and thickness profile are different between the subject devices and the predicate device.			

<b>Performance Data for Chemotherapy Drugs</b>				
<b>Standard</b>	<b>Subject Device Halyard Sterling SG* Nitrile Sensi- Guard Powder- Free Exam Gloves</b>	<b>Subject Device Halyard Sterling Nitrile Powder- Free Exam Gloves</b>	<b>Predicate K180646</b>	<b>Comparison</b>
<b>ASTM D6978-05</b>  Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Arsenic Trioxide (1 mg/ml), No breakthrough up to 240 minutes  Doxorubicin HCL (2 mg/ml), No breakthrough up to 240 minutes  Paclitaxel (6 mg/ml), No breakthrough up to 240 minutes  Azacitidine (Vidaza) (25 mg/ml), No breakthrough up to 240 minutes  Epirubicin (Ellence) (2 mg/ml), No breakthrough up to 240 minutes	Arsenic Trioxide (1 mg/ml), No breakthrough up to 240 minutes  Doxorubicin HCL (2 mg/ml), No breakthrough up to 240 minutes  Paclitaxel (6 mg/ml), No breakthrough up to 240 minutes  Azacitidine (Vidaza) (25 mg/ml), No breakthrough up to 240 minutes  Epirubicin (Ellence) (2 mg/ml), No breakthrough up to 240 minutes	No signs of breakthrough after 4 hours for 10 drugs.  Carmustine showed no signs of breakthrough until 0.3 minutes  Thiotepa showed no signs of breakthrough until 30.9 minutes.  Cyclophosphamide (20.0 mg/ml) No breakthrough up to 240 minutes  Doxorubicin HCL (2.0 mg/ml) No breakthrough up to 240 minutes	Similar

	Paraplatin (10 mg/ml), No breakthrough up to 240 minutes	Paraplatin (10 mg/ml), No breakthrough up to 240 minutes	Etoposide (20.0 mg/ml) No breakthrough up to 240 minutes
	Bendamustine (5 mg/ml), No breakthrough up to 240 minutes	Bendamustine (5 mg/ml), No breakthrough up to 240 minutes	5-Fluorouracil (50.0 mg/ml) No breakthrough up to 240 minutes
	Eribulin Mesylate (0.5 mg/ml), No breakthrough up to 240 minutes	Eribulin Mesylate (0.5 mg/ml), No breakthrough up to 240 minutes	Paclitaxel (Taxol) (6.0 mg/ml) No breakthrough up to 240 minutes
	Pemetrexed (25 mg/ml), No breakthrough up to 240 minutes	Pemetrexed (25 mg/ml), No breakthrough up to 240 minutes	Cisplatin (1.0 mg/ml) No breakthrough up to 240 minutes
	Bortezomib (Velcade) (1 mg/ml), No breakthrough up to 240 minutes	Bortezomib (Velcade) (1 mg/ml), No breakthrough up to 240 minutes	Dacarbazine (10.0 mg/ml) No breakthrough up to 240 minutes
	Etoposide (20 mg/ml), No breakthrough up to 240 minutes	Etoposide (20 mg/ml), No breakthrough up to 240 minutes	Ifosfamide (50.0 mg/ml) No breakthrough up to 240 minutes
	Pertuzumab (30 mg/ml), No breakthrough up to 240 minutes	Pertuzumab (30 mg/ml), No breakthrough up to 240 minutes	Mitoxantrone (2.0 mg/ml) No breakthrough up to 240 minutes
	Bleomycin sulfate (15 mg/ml), No breakthrough up to 240 minutes	Bleomycin sulfate (15 mg/ml), No breakthrough up to 240 minutes	Vincristine sulfate (1.0 mg/ml) No breakthrough up to 240 minutes
	Fludarabine (25 mg/ml), No breakthrough up to 240 minutes	Fludarabine (25 mg/ml), No breakthrough up to 240 minutes	Carmustine (3.3 mg/ml) No breakthrough up to 0.3 minutes

	Raltitrexed (0.5 mg/ml), No breakthrough up to 240 minutes	breakthrough up to 240 minutes	ThioTEPA (10.0 mg.ml) No breakthrough up to 30.9 minutes
	Busulfan (6 mg/ml), No breakthrough up to 240 minutes	Raltitrexed (0.5 mg/ml), No breakthrough up to 240 minutes	
	Fluorouracil (50 mg/ml), No breakthrough up to 240 minutes	Busulfan (6 mg/ml), No breakthrough up to 240 minutes	
	Retrovir (10 mg/ml) No breakthrough up to 240 minutes	Fluorouracil (50 mg/ml), No breakthrough up to 240 minutes,	
	Carboplatin (10 mg/ml), No breakthrough up to 240 minutes	Retrovir (10 mg/ml) No breakthrough up to 240 minutes	
	Fulvestrant (50 mg/ml), No breakthrough up to 240 minutes	Carboplatin (10 mg/ml), No breakthrough up to 240 minutes	
	Rituximab (10 mg/ml), No breakthrough up to 240 minutes	Fulvestrant (50 mg/ml), No breakthrough up to 240 minutes	
	Carfilzomib (2 mg/ml), No breakthrough up to 240 minutes	Rituximab (10 mg/ml), No breakthrough up to 240 minutes	
	Gemcitabine (38 mg/ml), No breakthrough up to 240 minutes	Carfilzomib (2 mg/ml), No breakthrough up to 240 minutes	
		Gemcitabine (38 mg/ml), No	

	<p>Temsirolimus (25 mg/ml), No breakthrough up to 240 minutes</p> <p>Cetuximab (Erbix) (2 mg/ml), No breakthrough up to 240 minutes</p> <p>Idarubicin (1 mg/ml), No breakthrough up to 240 minutes</p> <p>Trastuzumab (21 mg/ml), No breakthrough up to 240 minutes</p> <p>Cisplatin (1 mg/ml), No breakthrough up to 240 minutes</p> <p>Ifosfamide (50 mg/ml), No breakthrough up to 240 minutes</p> <p>Topotecan HCL (1 mg/ml), No breakthrough up to 240 minutes</p> <p>Cyclophosphamide (20 mg/ml), No breakthrough up to 240 minutes</p> <p>Irinotecan (20 mg/ml), No</p>	<p>breakthrough up to 240 minutes</p> <p>Temsirolimus (25 mg/ml), No breakthrough up to 240 minutes</p> <p>Cetuximab (Erbix) (2 mg/ml), No breakthrough up to 240 minutes</p> <p>Idarubicin (1 mg/ml), No breakthrough up to 240 minutes</p> <p>Trastuzumab (21 mg/ml), No breakthrough up to 240 minutes</p> <p>Cisplatin (1 mg/ml), No breakthrough up to 240 minutes</p> <p>Ifosfamide (50 mg/ml), No breakthrough up to 240 minutes</p> <p>Topotecan HCL (1 mg/ml), No breakthrough up to 240 minutes</p> <p>Cyclophosphamide (20 mg/ml), No breakthrough up to 240 minutes</p>		
--	--	---	--	--



	breakthrough up to 240 minutes	Irinotecan (20 mg/ml), No breakthrough up to 240 minutes		
	Triclosan (2 mg/ml), No breakthrough up to 240 minutes	Triclosan (2 mg/ml), No breakthrough up to 240 minutes		
	Cytarabine HCL (100 mg/ml), No breakthrough up to 240 minutes	Cytarabine HCL (100 mg/ml), No breakthrough up to 240 minutes		
	Mechlorethamine HCL (1 mg/ml), No breakthrough up to 240 minutes	Mechlorethamine HCL (1 mg/ml), No breakthrough up to 240 minutes		
	Trisonex (1 mg/ml), No breakthrough up to 240 minutes	Trisonex (1 mg/ml), No breakthrough up to 240 minutes		
	Cytovene (10 mg/ml), No breakthrough up to 240 minutes	Cytovene (10 mg/ml), No breakthrough up to 240 minutes		
	Melphalan (5 mg/ml), No breakthrough up to 240 minutes	Melphalan (5 mg/ml), No breakthrough up to 240 minutes		
	Vincristine Sulfate (1 mg/ml), No breakthrough up to 240 minutes	Vincristine Sulfate (1 mg/ml), No breakthrough up to 240 minutes		
	Dacarbazine (10 mg/ml), No breakthrough up to 240 minutes	Dacarbazine (10 mg/ml), No breakthrough up to 240 minutes		
	Methotrexate (25 mg/ml), No	Methotrexate (25 mg/ml), No		

	breakthrough up to 240 minutes,	Methotrexate (25 mg/ml), No breakthrough up to 240 minutes,		
	Vinblastine (1 mg/ml), No breakthrough up to 240 minutes	Vinblastine (1 mg/ml), No breakthrough up to 240 minutes		
	Daunorubicin HCL (5 mg/ml), No breakthrough up to 240 minutes	Daunorubicin HCL (5 mg/ml), No breakthrough up to 240 minutes		
	Mitomycin-C (0.5 mg/ml), No breakthrough up to 240 minutes	Mitomycin-C (0.5 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		
	Decitabine (5 mg/ml), No breakthrough up to 240 minutes	Decitabine (5 mg/ml), No breakthrough up to 240 minutes		
	Mitoxantrone (2 mg/ml), No breakthrough up to 240 minutes	Mitoxantrone (2 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		
	Docetaxel (10 mg/ml), No breakthrough up to 240 minutes	Docetaxel (10 mg/ml), No breakthrough up to 240 minutes		
	Oxaliplatin (2 mg/ml), No	Oxaliplatin (2 mg/ml), No		

	<p>breakthrough up to 240 minutes</p> <p>ThioTEPA (10 mg/ml), breakthrough detected at 23.9 minutes</p> <p>Carmustine (3.3 mg/ml), breakthrough detected at 14.8 minutes</p>	<p>Oxaliplatin (2 mg/ml), No breakthrough up to 240 minutes</p> <p>ThioTEPA (10 mg/ml), breakthrough detected at 37.1 minutes</p> <p>Carmustine (3.3 mg/ml), breakthrough detected at 22.9 minutes</p>		
--	--	--	--	--

<b>Summary of Non-Clinical Data</b>				
<b>Standard</b>	<b>Subject Device Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves</b>	<b>Subject Device Halyard Sterling Nitrile Powder-Free Exam Gloves</b>	<b>Acceptance Criteria</b>	<b>Results of Subject Devices</b>
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.	Must meet an AQL of 2.5% for leakage.	Pass
ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves	Residual powder on the subject device is an average of 0.03 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 0.03 mg/glove within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free.	Less than 2 mg maximum powder per glove.	Pass
ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications	Average Tensile Strength (before aging) = 35.2 MPa  Average Tensile Strength (after aging) = 44.1 MPa  Average Elongation (before aging) = 606%  Average Elongation (after aging) = 553%	Average Tensile Strength (before aging) = 37.2 MPa  Average Tensile Strength (after aging) = 41.6 MPa  Average Elongation (before aging) = 606%  Average Elongation (after aging) = 567%	Within the limits of the standard and the physical properties of the subject device met the requirements for tensile strength and elongation before and after aging.	Pass
<b>ISO 10993 Biological evaluation of medical devices</b>				

Systemic Toxicity Study in Mice -Saline and Sesame Oil Extracts	No mortality of evidence of systemic toxicity from the extracts – PASS	No mortality of evidence of systemic toxicity from the extracts – PASS	No animals treated with test extracted exhibited greater reaction than control animals.	Pass
Dermal Irritation	Based on the criteria and conditions of the study, the test article was considered non-irritating - PASS	Based on the criteria and conditions of the study, the test article was considered non-irritating - PASS	Primary Irritation Index $\leq$ Grade 1	Pass
Dermal Sensitization	Based on the criteria and conditions of the study, the test article showed no evidence of causing delayed dermal contact sensitization – PASS	Based on the criteria and conditions of the study, the test article showed no evidence of causing delayed dermal contact sensitization – PASS	Stimulation Index $\leq$ 3	Pass
<b>Conclusion:</b>	The conclusions drawn from the nonclinical tests demonstrate that the subject devices (Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves and Halyard STERLING* Nitrile Powder-Free Exam Gloves are as safe, as effective, and performs as well as or better than the legally marketed device cleared under K180646.			