March 22, 2024

O&M Halyard, Inc.
Caitlin Senter
Director, Global Regulatory Affairs
1 Edison Drive
Alpharetta, Georgia 30005

Re: K231938
Trade/Device Name: Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid; Halyard STERLING SG* SENSI-GUARD Powder-Free Nitrile Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid; Halyard STERLING NITRILE-XTRA * Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: February 23, 2024
Received: February 23, 2024

Dear Caitlin Senter:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (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.

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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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

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

510(k) Number *(if known)*
K231938

Device Name
Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid

Indications for Use *(Describe)*
The Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes:
Azacitidine (Vidaza) (25 mg/mL)
Bendamustine HCl (5 mg/mL)
Bleomycin Sulfate (Blenoxane) (15 mg/mL)
Bortezomib (Velcade) (1 mg/mL)
Busulfan (6 mg/mL)
Capecitabine (26 mg/mL)
Carboplatin (10 mg/mL)
Carfilzomib (2 mg/mL)
Cetuximab (Erbitux) (2 mg/mL)
Cisplatin (1 mg/mL)
Cladribine (1 mg/mL)
Cyclophosphamide (20 mg/mL)
Cytarabine HCl (Cytosine) (100 mg/mL)
Dacarbazine (DTIC) (10 mg/mL)
Dactinomycin (0.5 mg/mL)
Daunorubicin HCl (5 mg/mL)
Decitabine (5 mg/mL)
Docetaxel HCl (20 mg/mL)
Doxorubicin HCl (2 mg/mL)
Epirubicin HCl (Ellence) (2 mg/mL)
Etoposide (20 mg/mL)
Floxuridine (1 00mg/mL)
5-Fluorouracil (50 mg/mL)
Gemcitabine HCl (38 mg/mL)
Idarubicin HCl (1 mg/mL)
lfosfamide (IFEX) (50 mg/mL)
Irinotecan HCl (20 mg/mL)
Lenvatinib (20mg/mL)
Leuprolide Acetate Salt (5 mg/mL)
Mechlorethamine HCl (1 mg/mL)
Melphalan HCl (5 mg/mL)
Methotrexate (25 mg/mL)
Mitomycin C (0.5 mg/mL)
Mitoxantrone HCl (2 mg/mL)
Nelarabine (5 mg/mL)
Oxaliplatin (5 mg/mL)
Paclitaxel (Taxol) (6 mg/mL (6,000 ppm)
Pemetrexed (25 mg/mL)

Raltitrexed (0.5 mg/mL)
Sorafenib Tosylate (200 mg/mL)
Streptozocin (lO0mg/mL)
Tamoxifen (2 mg/mL)
Teniposide (10 mg/mL)
Topotecan HCl (1 mg/mL)
Trisenox (Arsenic Trioxide) (1 mg/mL)
Vinblastine Sulfate (1 mg/mL)
Vincristine Sulfate (Oncovin) (1 mg/mL)
Vinorelbine (10 mg/mL)

The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes:
Carmustine (3.3 mg/mL), breakthrough detected at 22.9 minutes

The following chemotherapy drugs and concentration showed breakthrough detected in less than 40 minutes:
ThioTEPA (10 mg/mL), breakthrough detected at 37.1 minutes

Warning: Do not use with Carmustine or ThioTEPA

The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes:
Fentanyl Citrate Injection (100 mcg/2 mL)
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection 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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Indications for Use

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

510(k) Number *(if known)*
K231938

Device Name
Halyard STERLING SG* SENSI-GUARD Powder-Free Nitrile Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid

Indications for Use *(Describe)*
The Halyard STERLING SG* SENSI-GUARD Powder-Free Nitrile Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes:
Azacitidine (Vidaza) (25 mg/mL)
Bendamustine HCl (5 mg/mL)
Bleomycin Sulfate (Blenoxane) (15 mg/mL)
Bortezomib (Velcade) (1 mg/mL)
Busulfan (6 mg/mL)
Capecitabine (26 mg/mL)
Carboplatin (10 mg/mL)
Carfilzomib (2 mg/mL)
Cetuximab (Erbitux) (2 mg/mL)
Cisplatin (1 mg/mL)
Cladribine (1 mg/mL)
Cyclophosphamide (20 mg/mL)
Cytarabine HCl (Cytosine) (100 mg/mL)
Dacarbazine (DTIC) (10 mg/mL)
Dactinomycin (0.5 mg/mL)
Daunorubicin HCl (5 mg/mL)
Decitabine (5 mg/mL)
Docetaxel HCl (20 mg/mL)
Doxorubicin HCl (2 mg/mL)
Epirubicin HCl (Ellence) (2 mg/mL)
Etoposide (20 mg/mL)
Eribulin Mesylate (0.5 mg/mL)
Fludarabine (25 mg/mL)
5-Fluorouracil (50 mg/mL)
Gemcitabine HCl (38 mg/mL)
Idarubicin HCl (1 mg/mL)
lfosfamide (IFEX) (50 mg/mL)
Irinotecan HCl (20 mg/mL)
Lenvatinib (20 mg/mL)
Leuprolide Acetate Salt (5 mg/mL)
Mechlorethamine HCl (1 mg/mL)
Melphalan HCl (5 mg/mL)
Methotrexate (25 mg/mL)
Mitomycin C (0.5 mg/mL)
Mitoxantrone HCl (2 mg/mL)
Oxaliplatin (5 mg/mL)
Paclitaxel (Taxol) (6 mg/mL (6,000 ppm)
Pemetrexed (25 mg/mL)

Raltitrexed (0.5 mg/mL)
Ritux1mab (10 mg/mL)
Sorafenib Tosylate (200 mg/mL)
Tamoxifen (2 mg/mL)
Topotecan HCl (1 mg/mL)
Trisenox (Arsenic Trioxide) (1 mg/mL)
Vinblastine Sulfate (1 mg/mL)
Vincristine Sulfate (Oncovin) (1 mg/mL)
Vinorelbine (10 mg/mL)

The following chemotherapy drugs and concentration showed breakthrough detected in less than 20 minutes:
Carmustine (BCNU) (3.3 mg/ml), breakthrough detected at 14.8 minutes

The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes:
ThioTEPA (10 mg/ml), breakthrough detected at 23.9 minutes

Warning: Do not use with Carmustine or ThioTEPA

The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes:
Fentanyl Citrate Injection (100 mcg/2 mL)
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes:
Cyclosporin A (100 mg/mL)
Cytovene (Ganciclovir) (10 mg/mL)
Retrovir (Zidovudine) (10 mg/mL)

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)

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Indications for Use

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

510(k) Number *(if known)*
K231938

Device Name
Halyard STERLING NITRILE-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid

Indications for Use *(Describe)*
The Halyard STERLING NITRILE-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes:
Azacitidine (Vidaza) (25 mg/mL)
Bendamustine HCl (5 mg/mL)
Bleomycin Sulfate (Blenoxane) (15 mg/mL)
Bortezomib (Velcade) (1 mg/mL)
Busulfan (6 mg/mL)
Capecitabine (26 mg/mL)
Carboplatin (10 mg/mL)
Carfilzomib (2 mg/mL)
Cetuximab (Erbitux) (2 mg/mL)
Cisplatin (1 mg/mL)
Cladribine (1 mg/mL)
Cyclophosphamide (20 mg/mL)
Cytarabine HCl (Cytosine) (100 mg/mL)
Dacarbazine (DTIC) (10 mg/mL)
Dactinomycin (0.5 mg/mL)
Daunorubicin HCl (5 mg/mL)
Decitabine (5 mg/mL)
Docetaxel HCl (20 mg/mL)
Doxorubicin HCl (2 mg/mL)
Epirubicin HCl (Ellence) (2 mg/mL)
Etoposide (20 mg/mL)
Floxuridine (100 mg/mL)
Fludarabine (25 mg/mL)
5-Fluorouracil (50 mg/mL)
Gemcitabine HCl (38 mg/mL)
Idarubicin HCl (1 mg/mL)
lfosfamide (IFEX) (50 mg/mL)
Irinotecan HCl (20 mg/mL)
Lenvatinib (20 mg/mL)
Leuprolide Acetate Salt (5 mg/mL)
Mechlorethamine HCl (1 mg/mL)
Melphalan HCl (5 mg/mL)
Methotrexate (25 mg/mL)
Mitomycin C (0.5 mg/mL)
Mitoxantrone HCl (2 mg/mL)
Nelarabine (5 mg/mL)
Oxaliplatin (5 mg/mL)
Paclitaxel (Taxol) (6 mg/mL (6,000 ppm)

Pemetrexed (25 mg/mL)
Ralt1trexed (0.5 mg/mL)
Rituximab (10 mg/mL)
Sorafenib Tosylate (200 mg/mL)
Streptozocin (100 mg/mL)
Tamoxifen (2 mg/mL)
Teniposide (10 mg/mL)
Topotecan HCl (1 mg/mL)
Trisenox (Arsenic Trioxide) (1 mg/mL)
Vinblastine Sulfate (1 mg/mL)
Vincristine Sulfate (Oncovin) (1 mg/mL)
Vinorelbine (10 mg/mL)

The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes:
Carmustine (3.3 mg/ml), breakthrough detected at 25.2 minutes

The following chemotherapy drugs and concentration showed breakthrough detected in less than 40 minutes:
ThioTEPA (10 mg/ml), breakthrough detected at 35.5 minutes

Warning: Do not use with Carmustine or ThioTEPA

The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes:
Fentanyl Citrate Injection (100 mcg/2 mL)
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection 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)

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510(k) Summary - K231938

Date Summary was Prepared	March 22, 2024
510(k) Submitter	O & M Halyard, Inc. 1 Edison Drive Alpharetta, GA 30005
Primary Contact for this 510(k) Submission	Caitlin Senter, MS, RAC Tel: 678-221-7330 Email: caitlin.senter@hyh.com
Marketed Common Name	Nitrile Powder-Free Exam Gloves
Device Submission Trade name and Description	Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid, Halyard STERLING SG* SENSI-GUARD Powder-Free Nitrile Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid Halyard STERLING NITRILE-XTRA * Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid
Device Common Name	Medical Exam Gloves
Device Product Code and Classification Name	LZA Class I, 21 CFR §880.6250 Patient Examination Glove LZC Class I, 21 CFR §880.6250 Patient Examination Glove, Specialty; OPJ Class I, 21 CFR §880.6250 Medical Gloves With Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs QDO Class I, 21 CFR §880.6250 Fentanyl and other opioid protection glove
Predicate Device	Halyard Sterling* Nitrile Powder-Free Exam Gloves, Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves (K191230)
Reference Device	Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K192241)

Subject Device Description	The subject devices are disposable, grey-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves that are packed in a cardboard dispenser box. The devices follow consensus standards: 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 – Tests for systemic toxicity. ISO 10993-23: 2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation ISO 10993-10: 2010 Biological evaluation of medical devices – Tests for skin sensitization

Indications for Use for Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid	The Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (Vidaza) (25 mg/mL) Bendamustine HCl (5 mg/mL) Bleomycin Sulfate (Blenoxane) (15 mg/mL) Bortezomib (Velcade) (1 mg/mL) Busulfan (6 mg/mL) Capecitabine (26 mg/mL) Carboplatin (10 mg/mL) Carfilzomib (2 mg/mL) Cetuximab (Erbitux) (2 mg/mL) Cisplatin (1 mg/mL) Cladribine (1 mg/mL) Cyclophosphamide (20 mg/mL) Cytarabine HCl (Cytosine) (100 mg/mL) Dacarbazine (DTIC) (10 mg/mL) Dactinomycin (0.5 mg/mL) Daunorubicin HCl (5 mg/mL) Decitabine (5 mg/mL) Docetaxel HCl (20 mg/mL) Doxorubicin HCl (2 mg/mL) Epirubicin HCl (Ellence) (2 mg/mL) Etoposide (20 mg/mL) Floxuridine (1 00mg/mL) 5-Fluorouracil (50 mg/mL) Gemcitabine HCl (38 mg/mL) Idarubicin HCl (1 mg/mL) lfosfamide (IFEX) (50 mg/mL) Irinotecan HCl (20 mg/mL) Lenvatinib (20mg/mL) Leuprolide Acetate Salt (5 mg/mL) Mechlorethamine HCl (1 mg/mL) Melphalan HCl (5 mg/mL) Methotrexate (25 mg/mL) Mitomycin C (0.5 mg/mL) Mitoxantrone HCl (2 mg/mL) Nelarabine (5 mg/mL) Oxaliplatin (5 mg/mL) Paclitaxel (Taxol) (6 mg/mL (6,000 ppm) Pemetrexed (25 mg/mL) Raltitrexed (0.5 mg/mL) Sorafenib Tosylate (200 mg/mL) Streptozocin (lO0mg/mL) Tamoxifen (2 mg/mL) Teniposide (10 mg/mL)

	Topotecan HCl (1 mg/mL) Trisenox (Arsenic Trioxide) (1 mg/mL) Vinblastine Sulfate (1 mg/mL) Vincristine Sulfate (Oncovin) (1 mg/mL) Vinorelbine (10 mg/mL) The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes: Carmustine (3.3 mg/mL), breakthrough detected at 22.9 minutes The following chemotherapy drugs and concentration showed breakthrough detected in less than 40 minutes: ThioTEPA (10 mg/mL), breakthrough detected at 37.1 minutes Warning: Do not use with Carmustine or ThioTEPA The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

Indications for Use for Halyard STERLING SG* SENSI-GUARD Powder-Free Nitrile Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid	The Halyard STERLING SG* SENSI-GUARD Powder-Free Nitrile Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (Vidaza) (25 mg/mL) Bendamustine HCl (5 mg/mL) Bleomycin Sulfate (Blenoxane) (15 mg/mL) Bortezomib (Velcade) (1 mg/mL) Busulfan (6 mg/mL) Capecitabine (26 mg/mL) Carboplatin (10 mg/mL) Carfilzomib (2 mg/mL) Cetuximab (Erbitux) (2 mg/mL) Cisplatin (1 mg/mL) Cladribine (1 mg/mL) Cyclophosphamide (20 mg/mL) Cytarabine HCl (Cytosine) (100 mg/mL) Dacarbazine (DTIC) (10 mg/mL) Dactinomycin (0.5 mg/mL) Daunorubicin HCl (5 mg/mL) Decitabine (5 mg/mL) Docetaxel HCl (20 mg/mL) Doxorubicin HCl (2 mg/mL) Epirubicin HCl (Ellence) (2 mg/mL) Etoposide (20 mg/mL) Eribulin Mesylate (0.5 mg/mL) Fludarabine (25 mg/mL) 5-Fluorouracil (50 mg/mL) Gemcitabine HCl (38 mg/mL) Idarubicin HCl (1 mg/mL) lfosfamide (IFEX) (50 mg/mL) Irinotecan HCl (20 mg/mL) Lenvatinib (20 mg/mL) Leuprolide Acetate Salt (5 mg/mL) Mechlorethamine HCl (1 mg/mL) Melphalan HCl (5 mg/mL) Methotrexate (25 mg/mL) Mitomycin C (0.5 mg/mL) Mitoxantrone HCl (2 mg/mL) Oxaliplatin (5 mg/mL) Paclitaxel (Taxol) (6 mg/mL (6,000 ppm) Pemetrexed (25 mg/mL) Raltitrexed (0.5 mg/mL) Ritux1mab (10 mg/mL) Sorafenib Tosylate (200 mg/mL) Tamoxifen (2 mg/mL) Topotecan HCl (1 mg/mL)

	Trisenox (Arsenic Trioxide) (1 mg/mL) Vinblastine Sulfate (1 mg/mL) Vincristine Sulfate (Oncovin) (1 mg/mL) Vinorelbine (10 mg/mL) The following chemotherapy drugs and concentration showed breakthrough detected in less than 20 minutes: Carmustine (BCNU) (3.3 mg/ml), breakthrough detected at 14.8 minutes The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes: ThioTEPA (10 mg/ml), breakthrough detected at 23.9 minutes Warning: Do not use with Carmustine or ThioTEPA The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Cyclosporin A (100 mg/mL) Cytovene (Ganciclovir) (10 mg/mL) Retrovir (Zidovudine) (10 mg/mL)

Indications for Use for Halyard STERLING NITRILE-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid	The Halyard STERLING NITRILE-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid are disposable devices Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (Vidaza) (25 mg/mL) Bendamustine HCl (5 mg/mL) Bleomycin Sulfate (Blenoxane) (15 mg/mL) Bortezomib (Velcade) (1 mg/mL) Busulfan (6 mg/mL) Capecitabine (26 mg/mL) Carboplatin (10 mg/mL) Carfilzomib (2 mg/mL) Cetuximab (Erbitux) (2 mg/mL) Cisplatin (1 mg/mL) Cladribine (1 mg/mL) Cyclophosphamide (20 mg/mL) Cytarabine HCl (Cytosine) (100 mg/mL) Dacarbazine (DTIC) (10 mg/mL) Dactinomycin (0.5 mg/mL) Daunorubicin HCl (5 mg/mL) Decitabine (5 mg/mL) Docetaxel HCl (20 mg/mL) Doxorubicin HCl (2 mg/mL) Epirubicin HCl (Ellence) (2 mg/mL) Etoposide (20 mg/mL) Floxuridine (100 mg/mL) Fludarabine (25 mg/mL) 5-Fluorouracil (50 mg/mL) Gemcitabine HCl (38 mg/mL) Idarubicin HCl (1 mg/mL) lfosfamide (IFEX) (50 mg/mL) Irinotecan HCl (20 mg/mL) Lenvatinib (20 mg/mL) Leuprolide Acetate Salt (5 mg/mL) Mechlorethamine HCl (1 mg/mL) Melphalan HCl (5 mg/mL) Methotrexate (25 mg/mL) Mitomycin C (0.5 mg/mL) Mitoxantrone HCl (2 mg/mL) Nelarabine (5 mg/mL) Oxaliplatin (5 mg/mL) Paclitaxel (Taxol) (6 mg/mL (6,000 ppm) Pemetrexed (25 mg/mL) Ralt1trexed (0.5 mg/mL) Rituximab (10 mg/mL) Sorafenib Tosylate (200 mg/mL) Streptozocin (100 mg/mL)

	Tamoxifen (2 mg/mL) Teniposide (10 mg/mL) Topotecan HCl (1 mg/mL) Trisenox (Arsenic Trioxide) (1 mg/mL) Vinblastine Sulfate (1 mg/mL) Vincristine Sulfate (Oncovin) (1 mg/mL) Vinorelbine (10 mg/mL) The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes: Carmustine (3.3 mg/ml), breakthrough detected at 25.2 minutes The following chemotherapy drugs and concentration showed breakthrough detected in less than 40 minutes: ThioTEPA (10 mg/ml), breakthrough detected at 35.5 minutes Warning: Do not use with Carmustine or ThioTEPA The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

Technological Characteristics Comparison Table						
	Subject Device Halyard STERLING* Nitrile Powder-Free Exam	**Subject Device Halyard STERLING SG* NITRILE Sensi-Guard Powder-Free Exam Gloves**	**Subject Device Halyard STERLING* NITRILE-XTRA* Powder-Free**	**Predicate Device K191230**	**Reference Device K192241**	**Comparison**
FDA Product Code	LZA, LZC, OPJ, QDO	LZA, LZC, OPJ, QDO	LZA, LZC, OPJ, QDO	LZC	LZA, LZC, QDO	Similar
FDA Classification	Class I	Class I	Class I	Class I	Class I	Same
Regulation Number	880.6250	880.6250	880.6250	880.6250	880.6250	Same
Common Name	Medical Exam Glove	Medical Exam Glove	Medical Exam Glove	Medical Exam Glove	Medical Exam Glove	Same
Device Trade Name	Halyard STERLING* Nitrile Powder-Free Exam Gloves	Halyard STERLING SG* NITRILE Sensi-Guard Powder-Free Exam Gloves	Halyard STERLING* NITRILE-XTRA* Powder-Free Exam Gloves	Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves Halyard Sterling Nitrile Powder-Free Exam Gloves	Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential, Powder-Free	Similar

Intended Use	The device with Low Dermatitis Potential, Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid 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, fentanyl citrate and gastric acid as listed on the label.	The device with Low Dermatitis Potential, Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid 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, fentanyl citrate and gastric acid as listed on the label.	The device with Low Dermatitis Potential, Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid 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, fentanyl citrate and gastric acid as listed on the label.	The devices 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 chemotherapy drugs as listed on the label.	The devices 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 low dermatitis potential and use with chemotherapy drugs and fentanyl citrate as listed on the label.	Similar
Technological Characteristics	Grey- colored, 9.5 inch, chlorinated, nitrile, 0.08 mm thick at palm, powder-free, textured fingertip, ambidextrous, non-sterile patient	Grey- colored, 9.5 inch, chlorinated, nitrile, 0.08 mm thick at palm, powder-free, textured fingertip, ambidextrous, non-sterile patient examination glove	Grey- colored, 12 inch, chlorinated, nitrile, 0.09 mm thick at palm, powder-free, textured fingertip, 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	Purple-colored, 12 inch, nitrile, 0.05 mm thick at palm powder-free, textured fingertip, ambidextrous, patient examination	Similar
Sizes of gloves	XS, S, M, L, XL	XS, S, M, L, XL	XS, S, M, L, XL	XS, S, M, L, XL	XS, S, M, L, XL	Same
Glove Length	9.5 inch	9.5 inch	12 inch	9.5 inch	12 inch	Similar
Texture	Textured fingertips	Textured fingertips	Textured fingertips	Textured fingertips	Textured fingertips	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Sterile	Similar

Performance Data						
Standard	**Subject Device Halyard STERLING* Nitrile Powder-Free Exam Gloves**	**Subject Device Halyard STERLING SG* NITRILE Sensi-Guard Powder-Free Exam Gloves**	**Subject Device Halyard STERLING* NITRILE-XTRA* Powder-Free**	**Predicate Device K191230**	**Reference Device K192241**	**Comparison**
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (Vidaza) (25 mg/mL) Bendamustine HCl (5 mg/mL) Bleomycin Sulfate (Blenoxane) (15 mg/mL) Bortezomib (Velcade) (1 mg/mL) Busulfan (6 mg/mL) Capecitabine (26 mg/mL) Carboplatin (10 mg/mL) Carfilzomib (2 mg/mL) Cetuximab (Erbitux) (2 mg/mL) Cisplatin (1 mg/mL) Cladribine (1 mg/mL) Cyclophosphamide (20 mg/mL) Cytarabine HCl (Cytosine) (100 mg/mL) Dacarbazine (DTIC) (10 mg/mL) Dactinomycin (0.5 mg/mL) Daunorubicin HCl (5 mg/mL) Decitabine (5 mg/mL) Docetaxel HCl (20 mg/mL) Doxorubicin HCl (2 mg/mL)	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (Vidaza) (25 mg/mL) Bendamustine HCl (5 mg/mL) Bleomycin Sulfate (Blenoxane) (15 mg/mL) Bortezomib (Velcade) (1 mg/mL) Busulfan (6 mg/mL) Capecitabine (26 mg/mL) Carboplatin (10 mg/mL) Carfilzomib (2 mg/mL) Cetuximab (Erbitux) (2 mg/mL) Cisplatin (1 mg/mL) Cladribine (1 mg/mL) Cyclophosphamide (20 mg/mL) Cytarabine HCl (Cytosine) (100 mg/mL) Dacarbazine (DTIC) (10 mg/mL) Dactinomycin (0.5 mg/mL) Daunorubicin HCl (5 mg/mL) Decitabine (5 mg/mL) Docetaxel HCl (20 mg/mL) Doxorubicin HCl (2 mg/mL)	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (Vidaza) (25 mg/mL) Bendamustine HCl (5 mg/mL) Bleomycin Sulfate (Blenoxane) (15 mg/mL) Bortezomib (Velcade) (1 mg/mL) Busulfan (6 mg/mL) Capecitabine (26 mg/mL) Carboplatin (10 mg/mL) Carfilzomib (2 mg/mL) Cetuximab (Erbitux) (2 mg/mL) Cisplatin (1 mg/mL) Cladribine (1 mg/mL) Cyclophosphamide (20 mg/mL) Cytarabine HCl (Cytosine) (100 mg/mL) Dacarbazine (DTIC) (10 mg/mL) Dactinomycin (0.5 mg/mL) Daunorubicin HCl (5 mg/mL) Decitabine (5 mg/mL) Docetaxel HCl (20 mg/mL) Doxorubicin HCl (2 mg/mL)	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	These gloves were tested for use with the following chemotherapy drugs and Fentanyl Citrate as per ASTM -D6978-05 : Aisenic Trioxide (I mg/ml) No breakthrough up to 240 minutes Azacitidine (Vidaza) (25 mg/ml) No breakthrough up to 240 minutes Bendamustine (5 mg/ml) No breakthrough up to 240 minutes Bortezomib (Velcade) (1 mg/ml) No breakthrough up to 240 minutes Bleomycin sulfate (15 mg/ml) No breakthrough up to 240 minutes Busulfan (6 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 169.8 minutes Cetuximab (Erbitux) (2 mg/ml) No	Similar

	Epirubicin HCl (Ellence) (2 mg/mL) Etoposide (20 mg/mL) Floxuridine (1 00mg/mL) 5-Fluorouracil (50 mg/mL) Gemcitabine HCl (38 mg/mL) Idarubicin HCl (1 mg/mL) lfosfamide (IFEX) (50 mg/mL) Irinotecan HCl (20 mg/mL) Lenvatinib (20mg/mL) Leuprolide Acetate Salt (5 mg/mL) Mechlorethamine HCl (1 mg/mL) Melphalan HCl (5 mg/mL) Methotrexate (25 mg/mL) Mitomycin C (0.5 mg/mL) Mitoxantrone HCl (2 mg/mL) Nelarabine (5 mg/mL) Oxaliplatin (5 mg/mL) Paclitaxel (Taxol) (6 mg/mL (6,000 ppm) Pemetrexed (25 mg/mL) Raltitrexed (0.5 mg/mL) Sorafenib Tosylate (200 mg/mL) Streptozocin (lO0mg/mL) Tamoxifen (2 mg/mL) Teniposide (10 mg/mL) Topotecan HCl (1 mg/mL) Trisenox (Arsenic Trioxide) (1 mg/mL) Vinblastine Sulfate (1 mg/mL)	Epirubicin HCl (Ellence) (2 mg/mL) Etoposide (20 mg/mL) Eribulin Mesylate (0.5 mg/mL) Fludarabine (25 mg/mL) 5-Fluorouracil (50 mg/mL) Gemcitabine HCl (38 mg/mL) Idarubicin HCl (1 mg/mL) lfosfamide (IFEX) (50 mg/mL) Irinotecan HCl (20 mg/mL) Lenvatinib (20 mg/mL) Leuprolide Acetate Salt (5 mg/mL) Mechlorethamine HCl (1 mg/mL) Melphalan HCl (5 mg/mL) Methotrexate (25 mg/mL) Mitomycin C (0.5 mg/mL) Mitoxantrone HCl (2 mg/mL) Oxaliplatin (5 mg/mL) Paclitaxel (Taxol) (6 mg/mL (6,000 ppm) Pemetrexed (25 mg/mL) Raltitrexed (0.5 mg/mL) Ritux1mab (10 mg/mL) Sorafenib Tosylate (200 mg/mL) Tamoxifen (2 mg/mL) Topotecan HCl (1 mg/mL) Trisenox (Arsenic Trioxide) (1 mg/mL) Vinblastine Sulfate (1 mg/mL) Vincristine Sulfate (Oncovin) (1	Epirubicin HCl (Ellence) (2 mg/mL) Etoposide (20 mg/mL) Floxuridine (100 mg/mL) Fludarabine (25 mg/mL) 5-Fluorouracil (50 mg/mL) Gemcitabine HCl (38 mg/mL) Idarubicin HCl (1 mg/mL) lfosfamide (IFEX) (50 mg/mL) Irinotecan HCl (20 mg/mL) Lenvatinib (20 mg/mL) Leuprolide Acetate Salt (5 mg/mL) Mechlorethamine HCl (1 mg/mL) Melphalan HCl (5 mg/mL) Methotrexate (25 mg/mL) Mitomycin C (0.5 mg/mL) Mitoxantrone HCl (2 mg/mL) Nelarabine (5 mg/mL) Oxaliplatin (5 mg/mL) Paclitaxel (Taxol) (6 mg/mL (6,000 ppm) Pemetrexed (25 mg/mL) Ralt1trexed (0.5 mg/mL) Rituximab (10 mg/mL) Sorafenib Tosylate (200 mg/mL) Streptozocin (100 mg/mL) Tamoxifen (2 mg/mL) Teniposide (10 mg/mL) Topotecan HCl (1 mg/mL) Trisenox (Arsenic	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 (Erbitux) (2	breakthrough up to 240 minutes Cisplatin (I mg/ml) No breakthrough up to 240 minutes Cladtibine (1 0 mg/ml) No breakthrough up to 240 minutes Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes Cytarabme 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 Daunorubicin HCL (5 mg/ml) No breakthrough up to 240 minutes Decitabine (5 mg/ml) No breakthrough up to 240 minutes Docetaxel (IO mg/ml) No breakthrough up to 240 minutes Doxoiubicin HCL (2 mg/ml) No breakthrough up to 240 minutes Epnubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes Etopos1de (20 mg/ml) No breakthrough up to 240 minutes Fludarabme (25 mg/ml) No breakthrough up to 240 minutes Fluorouracil (50 mg/ml) No breakthrough up	

	Vincristine Sulfate (Oncovin) (1 mg/mL) Vinorelbine (10 mg/mL) The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes: Carmustine (3.3 mg/mL), breakthrough detected at 22.9 minutes The following chemotherapy drugs and concentration showed breakthrough detected in less than 40 minutes: ThioTEPA (10 mg/mL), breakthrough detected at 37.1 minutes Warning: Do not use with Carmustine or ThioTEPA The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution	mg/mL) Vinorelbine (10 mg/mL) The following chemotherapy drugs and concentration showed breakthrough detected in less than 20 minutes: Carmustine (BCNU) (3.3 mg/ml), breakthrough detected at 14.8 minutes The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes: ThioTEPA (10 mg/ml), breakthrough detected at 23.9 minutes Warning: Do not use with Carmustine or ThioTEPA The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution The following	Trioxide) (1 mg/mL) Vinblastine Sulfate (1 mg/mL) Vincristine Sulfate (Oncovin) (1 mg/mL) Vinorelbine (10 mg/mL) The following chemotherapy drugs and concentration showed breakthrough detected in less than 30 minutes: Carmustine (3.3 mg/ml), breakthrough detected at 25.2 minutes The following chemotherapy drugs and concentration showed breakthrough detected in less than 40 minutes: ThioTEPA (10 mg/ml), breakthrough detected at 35.5 minutes Warning: Do not use with Carmustine or ThioTEPA The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection	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 Vincrinstine Sulfate (1 mg/ml),	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 hinotecan (20 mg/ml) No breakthrough up to 240 minutes Mechlorethamine HCL (1 mg/ml) No breakthrough up to 240 minutes Melphalan (5 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 MitoxantI one (2 mg/ml) No breakthrough up to 240 minutes Oxaliplatm (2 mg/ml) No breakthrough up to 240 minutes Pachtaxel (6 mg/ml) No b1eakth10ugh up to 240 minutes Paraplatm (10 mg/ml) No breakthrough up to 240 minutes Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes	

		hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Cyclosporin A (100 mg/mL) Cytovene (Ganciclovir) (10 mg/mL) Retrovir (Zidovudine) (10 mg/mL)	Mix 50/50 Solution	No breakthrough up to 240 minutes FORM FDA 3881 (7/17) Page 2 of 2 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	Pertuzumab (30 mg/ml) No breakthrough up to 240 minutes Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes Retrovn (IO mg/ml) No breakthrough up to 240 minutes Rituximab (l O mg/ml) No breakthrough up to 240 minutes Temsuolimus (25 mg/ml) No b1eakthrough up to 240 minutes Tiastuzumab (21 mg/ml) No breakth1ough up to 240 minutes ThioTEPA (10 mg/ml) No b1eakthrough up to 240 minutes Topotecan HCL (I mg/ml) No b1eakth1ough up to 240 minutes Triclosan (I mg/ml) No breakth10ugh up to 240 minutes Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes Vincrinstme Sulfate (1 mg/ml) No breakthrough up to 240 minutes Vinblastine (I mg/ml) No b1eakthrough up to 240 minutes Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes Zoledronic Acid (0.8 mg/ml) No breakth10ugh up to 240 minutes Fentanyl Citrate (100mcg/2ml) No	

				minutes. 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	breakth10ugh up to 240 minutes	

				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 (Erbitux) (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 Vincrinstine Sulfate (1 mg/ml), No breakthrough up to 240 minutes FORM FDA 3881 (7/17) Page 2 of 2 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.		

PERFORMANCE CHARACTERISTICS OF THE SUBJECT DEVICE

Performance Data			
	Subject Devices	Predicate Device	Comparison
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 predicate 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 within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free.	Residual powder on the predicate device is 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 physical dimensions of the predicate 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.	Same
ISO 10993-11: 2017 Biological evaluation of medical devices – Tests for systemic toxicity	Under the conditions of the study, the test article did not elicit acute systemic toxicity.	Under the conditions of the study, the test article did not elicit acute systemic toxicity.	Same
ISO 10993-23: 2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation	Under the conditions of the study, the test article was considered non-irritating.	Under the conditions of the study, the test article was considered non-irritating.	
ISO 10993-10: 2010 Biological evaluation of medical devices – Tests for skin sensitization.	Under the conditions of the study, the test article was considered non-sensitizing.	Under the conditions of the study, the test article was considered non-sensitizing.	

Clinical test	A 204 subject study was completed to evaluate whether the level of residual chemical additives in the subject device induced Type IV allergic contact sensitization by repetitive applications to the skin of normal healthy human volunteers using the Jordan-King modification of the Draize test as recommended by the FDA. Under the conditions of the study, the subject device was nonirritating and showed no clinical evidence of residual chemical additives that may induce Type IV allergy in human subject	Not previously tested.	Different
Conclusion:	The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject devices Halyard STERLING* Nitrile Powder-Free Exam Gloves ,Halyard STERLING SG* NITRILE Sensi-Guard Powder-Free Exam Gloves, and Halyard STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claims, are as safe, as effective, and performs as well as or better than the legally marketed device cleared under K191230.		