August 18, 2025

O&M Halyard, Inc.
Caitlin Senter
Director, Global Regulatory Affairs
1220 Old Alpharetta Rd.
Ste. 320
Alpharetta, Georgia 30005

Re: K243604
Trade/Device Name: Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated 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: November 21, 2024
Received: July 7, 2025

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.

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K243604

Device Name
Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated Gastric Acid

Indications for Use *(Describe)*
Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated 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:
Arsenic Trioxide (1 mg/ml)
Bendamustine, (5 mg/ml)
Blenoxane (15 mg/ml)
Bleomycin (15 mg/ml)
Bortezomib (1 mg/ml)
Busulfan (6 mg/ml)
Carboplatln (10 mg/ml)
Carfilzomib (2 mg/ml)
Cetuximab (2 mg/ml)
Cisplatin (1 mg/ml)
Cyclophosphamide (Cytoxan) (20 mg/ml)
Cytarabine (100 mg/ml)
Dacarbazine (DTIC) {10 mg/ml)
Daunorubicin {5 mg/ml)
Decitabine (5 mg/ml)
Docetaxel (10 mg/ml)
Doxorubicin HCL (2 mg/ml)
Ellence (2 mg/ml)
Erbitux (2 mg/ml)
Eribilin Mesylate (0.5 mg/ml)
Etoposide (Toposar) (20 mg/ml)
Fludarabine (25 mg/ml)
Fulvestrant (50 mg/ml)
Gemcitabine (Gemzar) (38 mg/ml)
ldarubicin (1 mg/ml)
lfosfamide (IFEX) (50 mg/ml)
lrinotecan (20 mg/ml)
Mechlorethamine HCL (1 mg/ml)
Melphalan (5 mg/ml)
Methotrexate (25 mg/ml)
Mitomycin C (0.5 mg/ml)
Mitoxantrone (2 mg/ml)
Oxaliplatin (2 mg/ml)
Paclitaxel (Taxol) (6 mg/ml)
Paraplatin (10 mg/ml)
Pemetrexed Disodium (25 mg/ml)
Pertuzumab (30 mg/ml)
Raltitrexed (0.5 mg/ml)

Rituximab (Rituxan) (10 mg/ml)
Temsirolimus (25 mg/ml)
Thiotepa (10 mg/ml)
Topotecan HCL (1 mg/ml)
Trastuzumab (21 mg/ml)
Trisenox (1 mg/ml)
Velcade (1 mg/ml)
Vinblastine (1 mg/ml)
Vinorelbine (10 mg/ml)

Carmustine (3.3 mg/ml) permeation occurred at 60.0 minutes.

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

Caution: Testing showed a minimum breakthrough time of 60.0 minutes with Carmustine.

The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes:
Cytovene (10 mg/ml)
Retrovir (10 mg/ml)
Triclosan (2 mg/ml)
Zoledronic Acid (0.8 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for K243604

This summary of 510(k) K243604 is being submitted in accordance with 21 CFR 807.92.

Date Summary was Prepared	July 31, 2025
510(k) Submitter	O&M Halyard, Inc. 1220 Old Alpharetta Rd., Ste. 320 Alpharetta, GA 30005
Primary Contact for this 510(k) Submission	Caitlin Senter, MS, RAC Tel: 678-221-7330 Email: caitlin.senter@owens-minor.com
Marketed Device Trade Name	Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated Gastric Acid
Device Submission Trade name and Description	Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated 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 medical 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* PURPLE NITRILE - XTRA* Powder Free-Exam Gloves (K160709)
Reference Device	Halyard Purple Nitrile* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (K241909)
Subject Device Description	The Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated Gastric Acid are disposable, 12"purple-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves.

Indications for Use	Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated 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: Arsenic Trioxide (1 mg/ml) Bendamustine, (5 mg/ml) Blenoxane (15 mg/ml) Bleomycin (15 mg/ml) Bortezomib (1 mg/ml) Busulfan (6 mg/ml) Carboplatln (10 mg/ml) Carfilzomib (2 mg/ml) Cetuximab (2 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (Cytoxan) (20 mg/ml) Cytarabine (100 mg/ml) Dacarbazine (DTIC) {10 mg/ml) Daunorubicin {5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCL (2 mg/ml) Ellence (2 mg/ml) Erbitux (2 mg/ml) Eribilin Mesylate (0.5 mg/ml) Etoposide (Toposar) (20 mg/ml) Fludarabine (25 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (Gemzar) (38 mg/ml) ldarubicin (1 mg/ml) lfosfamide (IFEX) (50 mg/ml) lrinotecan (20 mg/ml) Mechlorethamine HCL (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (2 mg/ml) Paclitaxel (Taxol) (6 mg/ml) Paraplatin (10 mg/ml) Pemetrexed Disodium (25 mg/ml) Pertuzumab (30 mg/ml) Raltitrexed (0.5 mg/ml) Rituximab (Rituxan) (10 mg/ml) Temsirolimus (25 mg/ml) Thiotepa (10 mg/ml) Topotecan HCL (1 mg/ml) Trastuzumab (21 mg/ml) Trisenox (1 mg/ml) Velcade (1 mg/ml) Vinblastine (1 mg/ml)

	Vinorelbine (10 mg/ml) Carmustine (3.3 mg/ml) permeation occurred at 60 minutes. The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 ml) Gastric Acid Fluid/Fentanyl Citrate Injection Mix (50/50 Solution) Caution: Testing showed a minimum breakthrough time of 60 minutes with Carmustine. The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Cytovene (10 mg/ml) Retrovir (10 mg/ml) Triclosan (2 mg/ml) Zoledronic Acid (0.8 mg/ml)

Technological Characteristics Comparison Table				
	Subject Device	Predicate Device (K160709)	Reference Device (K241909)	Comparison
FDA Product Code	LZA, LZC, OPJ, QDO	LZC	LZA, LZC, OPJ, QDO	Similar
FDA Classification	Class I	Class I	Class I	Same
Regulation Number	880.6250	880.6250	880.6250	Same
Common Name	Patient Examination Glove	Patient Examination Glove	Patient Examination Glove	Same
Device Trade Name	Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves	HAYLARD* PURPLE NITRILE – XTRA* Powder Free Exam Gloves	Halyard Purple Nitrile* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid	Similar

Intended Use/Indications for Use	Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated 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: Arsenic Trioxide (1 mg/ml) Bendamustine, (5 mg/ml) Blenoxane (15 mg/ml) Bleomycin (15 mg/ml) Bortezomib (1 mg/ml) Busulfan (6 mg/ml) Carboplatln (10 mg/ml) Carfilzomib (2 mg/ml) Cetuximab (2 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (Cytoxan) (20 mg/ml) Cytarabine (100 mg/ml) Dacarbazine (DTIC) {10 mg/ml) Daunorubicin {5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCL (2 mg/ml) Ellence (2 mg/ml) Erbitux (2 mg/ml) Eribilin Mesylate (0.5 mg/ml) Etoposide (Toposar) (20	HALYARD* PURPLE NITRILE - XTRA* Powder Free Exam Gloves tested for Use with Chemotherapy Drugs are powder-free patient examination gloves that are a disposable device intended for medical purposes worn on the examiner's hand or finger to prevent contamination between patient and examiner. This is an over the counter medical device. HALYARD* PURPLE NITRILE - XTRA* Powder Pree Exam Gloves have been tested with the following Chemotherapy drugs showing no breakthrough up to 240 minutes. Carmustine showed breakthrough at 80.4 minutes Arsenic Trioxide (1 mg/ml) Azacitidine (Vidaza) (25 mg/ml) Bendamustine (5 mg/ml) Bleomycin Sulfate (15 mg/ml) Bortezomib (Velcade) (1 mg/ml) Busulfan (6 mg/ml) Carlzomib (2 mg/ml) Carboplatin (10 mg/ml) Carmustine (3.3 mg/ml) Cetuximab (Erbitux) (2 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCl (100 mg/ml) Cytovene (10 mg/ml) Dacarbazine (10 mg/ml)	Halyard Purple Nitrile* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid are disposable devices 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 and Gastric Acid as per ASTM -D6978-05: The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (25 mg/ml) Bendamustine HCl (5 mg/ml) Bleomycin Sulfate (15 mg/ml) Bortezomib (1 mg/ml) Busulfan (6 mg/ml) Capecitabine (26 mg/ml) Carboplatin (10 mg/ml) Carlzomib (2 mg/ml) Cetuximab (2 mg/ml) Chloroquine (50 mg/ml) Cisplatin (1 mg/ml) Cladribine (1 mg/ml) Cyclophosphamide (20 mg/ml) Cyclosporin A (100 mg/ml)	Similar Adding Low Dermatitis Potential claim to subject device as compared to reference predicate

	mg/ml) Fludarabine (25 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (Gemzar) (38 mg/ml) ldarubicin (1 mg/ml) lfosfamide (IFEX) (50 mg/ml) lrinotecan (20 mg/ml) Mechlorethamine HCL (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (2 mg/ml) Paclitaxel (Taxol) (6 mg/ml) Paraplatin (10 mg/ml) Pemetrexed Disodium (25 mg/ml) Pertuzumab (30 mg/ml) Raltitrexed (0.5 mg/ml) Rituximab (Rituxan) (10 mg/ml) Temsirolimus (25 mg/ml) Thiotepa (10 mg/ml) Topotecan HCL (1 mg/ml) Trastuzumab (21 mg/ml) Trisenox (1 mg/ml) Velcade (1 mg/ml) Vinblastine (1 mg/ml) Vinorelbine (10 mg/ml) Carmustine (3.3 mg/ml) permeation occurred at 60 minutes. The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes:	Daunorubicin Hcl (5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCl (2 mg/ml) Ellence (2 mg/ml) Eribulin Mesylate (0.5 mg/ml) Etoposid (20 mg/ml) Fludarabine (25 mg/ml) Fulvestrant (50 mg/ml) Fluorouracil (50 mg/ml) Gemcitabine (38 mg/ml) Idarubicin (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan (20 mg/ml) Mechlorethamine HCl (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (5 mg/ml) Paclitaxel (6 mg/ml) Paraplatin (10 mg/ml) Pemetrexed (25 mg/ml) Pertuzumab (30 mg/ml) Raltitrexed (0.5 mg/ml) Retrovir (10 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Thiotepa (10 mg/ml) Topotecan HCl (1 mg/ml) Trastuzumab (21 mg/ml) Triclosan (1 mg/ml) Trisenox (0.1 mg/ml) Vinblastine (1 mg/ml) Vincristine Sulfate (1 mg/ml) Vinorelbine (10 mg/ml) Zoledronic Acid (0.8 mg/ml)	Cytarabine (Cytosine) (100 mg/ml) Cytovene (Ganciclovir) (10 mg/ml) Dacarbazine (DTIC) (10 mg/ml) Dactinomycin (0.5 mg/ml) Daunorubicin HCl (5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCl (2 mg/ml) Epirubicin HCl (Ellence) (2 mg/ml) Etoposide (Toposar) (20 mg/ml) Fludarabine (25 mg/ml) 5-Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (38 mg/ml) Idarubicin (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan HCl (20 mg/ml) Leuprolide Acetate Salt (5 mg/ml) Mechlorethamine HCl (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (5 mg/ml) Paclitaxel (6 mg/ml) Pemetrexed (25 mg/ml) Raltitrexed (0.5 mg/ml) Retrovir (10 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Topotecan HCl (1 mg/ml) Triclosan (2 mg/ml)	

	Fentanyl Citrate Injection (100 mcg/2 ml) Gastric Acid Fluid/Fentanyl Citrate Injection Mix (50/50 Solution) Caution: Testing showed a minimum breakthrough time of 60 minutes with Carmustine. The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Cytovene (10 mg/ml) Retrovir (10 mg/ml) Triclosan (2 mg/ml) Zoledronic Acid (0.8 mg/ml)		Trisenox (1 mg/ml) Vinblastine Sulfate (1 mg/ml) Vincristine (1 mg/ml) Vinorelbine (10 mg/ml) Zoledronic Acid (0.8 mg/ml) The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes: Carmustine (3.3 mg/ml) No breakthrough up to 55.3 minutes. Thiotepa (10 mg/ml) No breakthrough up to 78.8 minutes. Warning- Not for use with Carmustine and 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) (50 mcg/2 ml)	

Technological Characteristics	Colored, 12 inch, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination glove	Colored, 12 inch, chlorinated, nitrile, powder-free, textured fingertips, ambidextrous, non-sterile patient examination glove	Colored, 9.5 inch, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination glove	Similar
Sizes of gloves	XS, S, M, L, XL, XXL	XS, S, M, L, XL	XS, S, M, L, XL, XXL	Similar Adding XXL size to subject device
Color	Purple	Purple	Purple	Similar
Texture	Textured fingertips	Textured fingertips	Textured fingertips	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Biocompatibility	Based on ISO 10993, Part 11 Biological Evaluation of Medical Devices – Test for systemic toxicity, the test article was considered non- toxic. Meets the acceptance criteria.	Based ISO 10993 Biological Evaluation of Medical devices – Test for systemic toxicity, the test article was considered non-toxic. Meets the acceptance criteria.	Based on ISO 10993, Part 11 Biological Evaluation of Medical Devices – Test for systemic toxicity, the test article was considered non- toxic. Meets the acceptance criteria.	Same
	Based on ISO 10993, Part 23- Biological Evaluation of Medical Devices – Test for irritation, the test article was considered non-irritant. Meets the acceptance criteria.	Based on ISO 10993, Part 10- Biological Evaluation of Medical Devices – Test for irritation, the test article was considered non- irritant. Meets the acceptance criteria.	Based on ISO 10993, Part 23- Biological Evaluation of Medical Devices – Test for irritation, the test article was considered non-irritant. Meets the acceptance criteria.	
	Based on ISO 10993, Part 10 - Biological Evaluation of Medical Devices – Test for skin sensitization, the test article was considered a non- sensitizer. Meets the acceptance criteria.	Based on ISO 10993, Part 10 - Biological Evaluation of Medical Devices – Test for skin sensitization, the test article was considered non-sensitizer. Meets the acceptance criteria.	Based on ISO 10993, Part 10 - Biological Evaluation of Medical Devices – Test for skin sensitization, the test article was considered a non- sensitizer. Meets the acceptance criteria.	

Performance Data for Chemotherapy Drugs				
Standard	Subject Device	Predicate Device (K160709)	Reference Device (K241909)	Remarks
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: Arsenic Trioxide (1 mg/ml) Bendamustine, (5 mg/ml) Blenoxane (15 mg/ml) Bleomycin (15 mg/ml) Bortezomib (1 mg/ml) Busulfan (6 mg/ml) Carboplatln (10 mg/ml) Carfilzomib (2 mg/ml) Cetuximab (2 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (Cytoxan) (20 mg/ml) Cytarabine (100 mg/ml) Dacarbazine (DTIC) {10 mg/ml) Daunorubicin {5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCL (2 mg/ml) Ellence (2 mg/ml) Erbitux (2 mg/ml) Eribilin Mesylate (0.5 mg/ml) Etoposide (Toposar) (20 mg/ml) Fludarabine (25 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (Gemzar) (38 mg/ml) ldarubicin (1 mg/ml) lfosfamide (IFEX) (50 mg/ml) lrinotecan (20 mg/ml) Mechlorethamine HCL (1 mg/ml)	HALYARD* PURPLE NITRILE - XTRA* Powder Pree Exam Gloves have been tested with the following Chemotherapy drugs showing no breakthrough up to 240 minutes. Carmustine showed breakthrough at 80.4 minutes Arsenic Trioxide (1 mg/ml) Azacitidine (Vidaza) (25 mg/ml) Bendamustine (5 mg/ml) Bleomycin Sulfate (15 mg/ml) Bortezomib (Velcade) (1 mg/ml) Busulfan (6 mg/ml) Carlzomib (2 mg/ml) Carboplatin (10 mg/ml) Carmustine (3.3 mg/ml) Cetuximab (Erbitux) (2 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCl (100 mg/ml) Cytovene (10 mg/ml) Dacarbazine (10 mg/ml) Daunorubicin Hcl (5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCl (2 mg/ml) Ellence (2 mg/ml) Eribulin Mesylate (0.5 mg/ml) Etoposide (20 mg/ml) Fludarabine (25 mg/ml)	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (25 mg/ml) Bendamustine HCl (5 mg/ml) Bleomycin Sulfate (15 mg/ml) Bortezomib (1 mg/ml) Busulfan (6 mg/ml) Capecitabine (26 mg/ml) Carboplatin (10 mg/ml) Carlzomib (2 mg/ml) Cetuximab (2 mg/ml) Chloroquine (50 mg/ml) Cisplatin (1 mg/ml) Cladribine (1 mg/ml) Cyclophosphamide (20 mg/ml) Cyclosporin A (100 mg/ml) Cytarabine (Cytosine) (100 mg/ml) Cytovene (Ganciclovir) (10 mg/ml) Dacarbazine (DTIC) (10 mg/ml) Dactinomycin (0.5 mg/ml) Daunorubicin HCl (5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCl (2 mg/ml) Epirubicin HCl (Ellence) (2 mg/ml) Etoposide (Toposar) (20 mg/ml)	Similar

	Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (2 mg/ml) Paclitaxel (Taxol) (6 mg/ml) Paraplatin (10 mg/ml) Pemetrexed Disodium (25 mg/ml) Pertuzumab (30 mg/ml) Raltitrexed (0.5 mg/ml) Rituximab (Rituxan) (10 mg/ml) Temsirolimus (25 mg/ml) Thiotepa (10 mg/ml) Topotecan HCL (1 mg/ml) Trastuzumab (21 mg/ml) Trisenox (1 mg/ml) Velcade (1 mg/ml) Vinblastine (1 mg/ml) Vinorelbine (10 mg/ml) Carmustine (3.3 mg/ml) permeation occurred at 60 minutes. **Caution:** Testing showed a minimum breakthrough time of 60 minutes with Carmustine. The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Cytovene (10 mg/ml) Retrovir (10 mg/ml) Triclosan (2 mg/ml) Zoledronic Acid (0.8 mg/ml)	Fulvestrant (50 mg/ml) Fluorouracil (50 mg/ml) Gemcitabine (38 mg/ml) Idarubicin (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan (20 mg/ml) Mechlorethamine HCl (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (5 mg/ml) Paclitaxel (6 mg/ml) Paraplatin (10 mg/ml) Pemetrexed (25 mg/ml) Pertuzumab (30 mg/ml) Raltitrexed (0.5 mg/ml) Retrovir (10 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Thiotepa (10 mg/ml) Topotecan HCl (1 mg/ml) Trastuzumab (21 mg/ml) Triclosan (1 mg/ml) Trisenox (0.1 mg/ml) Vinblastine (1 mg/ml) Vincristine Sulfate (1 mg/ml) Vinorelbine (10 mg/ml) Zoledronic Acid (0.8 mg/ml)	Fludarabine (25 mg/ml) 5-Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (38 mg/ml) Idarubicin (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan HCl (20 mg/ml) Leuprolide Acetate Salt (5 mg/ml) Mechlorethamine HCl (1 mg/ml) Melphalan (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2 mg/ml) Oxaliplatin (5 mg/ml) Paclitaxel (6 mg/ml) Pemetrexed (25 mg/ml) Raltitrexed (0.5 mg/ml) Retrovir (10 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Topotecan HCl (1 mg/ml) Triclosan (2 mg/ml) Trisenox (1 mg/ml) Vinblastine Sulfate (1 mg/ml) Vincristine (1 mg/ml) Vinorelbine (10 mg/ml) Zoledronic Acid (0.8 mg/ml) The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes: Carmustine (3.3 mg/ml) No breakthrough up to	

			55.3 minutes. Thiotepa (10 mg/ml) No breakthrough up to 78.8 minutes. Warning- Not for use with Carmustine and ThioTEPA	
Performance Data for Hazardous Drugs (opioids)				
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 ml) Gastric Acid Fluid/Fentanyl Citrate Injection Mix (50/50 Solution)	Not previously tested	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	Similar

Performance Data				
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.	Testing of the reference 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 predicate 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 reference 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	The physical dimensions of the subject device are	The physical dimensions of the predicate device are within the limits of	The physical dimensions of the reference device are	Same

Nitrile Examination Gloves for Medical Applications	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 standard and the physical properties of the predicate device met the requirements for tensile strength before and after aging. The predicate device also met the requirement for elongation before and after aging.	within the limits of the standard and the physical properties of the reference device met the requirements for tensile strength before and after aging. The reference device also met the requirement for elongation before and after aging.	
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 subjects.	Not previously tested	A 204 subject study was completed to evaluate whether the level of residual chemical additives in the reference 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 reference device was nonirritating and showed no clinical evidence of residual chemical additives that may induce Type IV allergy in human subjects.	Different

SUMMARY OF NON-CLINICAL TESTING

Brief description of non-clinical tests:	Test	Standard	Acceptance Criteria	Results
	Dimensions	ASTM D 6319 Length Palm Width Size Finger thickness Palm thickness Cuff thickness	 ≥230 mm X-Small: 60 – 80 mm Small: 70 - 90 mm Med: 85–105 mm Large: 100 - 120 mm X-Large: 110-130 mm XX-Large: 120-140 mm ≥0.05 mm ≥0.05 mm ≥0.05 mm	Meets requirements
	Physical Properties	ASTM D 6319	AQL 4.0 Before Aging Tensile Strength: ≥14 MPa Ultimate elongation: ≥500% After Aging Tensile Strength: ≥14 MPa Ultimate elongation: ≥400%	Meets requirements
	Freedom from Pinholes	ASTM D 6319 ASTM D 5151	AQL 2.5% No leakage	Meets requirements
	Powder Free	ASTM D 6124 ASTM D 6319	≤ 2 mg / glove	Meets requirements
	Test for irritation	ISO 10993, Part 23	≤ 0.4	Under the conditions of the study, the device is not an irritant.
	Test for acute systemic toxicity	ISO 10993, Part 11	No animals treated with test extracts exhibit greater reaction than control animals.	Under the conditions of the study, no evidence of acute systemic toxicity.
	Test for skin sensitization	ISO 10993, Part 10	Grade < 1.0	Under the conditions of the study, the device is not a sensitizer.

	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	ASTM D6978-05	No breakthrough for up to 240 minutes	51 Drugs tested showed minimum breakthrough detection time up to 240 minutes Carmustine 3.3mg/ml minimum breakthrough detection time is 60 minutes Fentanyl Citrate Injection (100 mcg/2 ml) Gastric Acid Fluid/Fentanyl Citrate Injection Mix (50/50 Solution) minimum breakthrough detection time up to 240 minutes.

SUMMARY OF CLINICAL TESTING

Test	Description	Results
Modified DRAIZE-95 Test to Evaluate Low Dermatitis Potential of Medical Gloves	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 subjects.

Conclusion:	The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject device, Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated Gastric Acid, are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K160709.