June 18, 2025

O&M Halyard, Inc.
Caitlin Senter
Director, Global Regulatory Affairs
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K243172
Trade/Device Name: Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs; Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Singles
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: September 30, 2024
Received: May 9, 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)*
K243172

Device Name
Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs;
Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Singles

Indications for Use *(Describe)*
The Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs or Sterile Singles, 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 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 (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)
Carfilzomib (2 mg/ml)
Cetuximab (2 mg/ml)
Cisplatin (1 mg/ml)
Cladribine (1 mg/ml)
Cyclophosphamide (20 mg/ml)
Cytarabine HCl (100 mg/ml)
Dacarbazine (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 (2 mg/ml)
Etoposide (20 mg/ml)
Fludarabine Phosphate (25 mg/ml)
Fluorouracil (50 mg/ml)
Fulvestrant (50 mg/ml)
Gemcitabine HCl (38 mg/ml)
Idarubicin HCl (1 mg/ml)
Ifosfamide (50 mg/ml)
Irinotecan HCl (20 mg/ml)
Leuprolide Acetate (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 (6 mg/ml)
Pemetrexed (25 mg/ml)

Raltitrexed (0.5 mg/ml)
Rituximab (10 mg/ml)
Temsirolimus (25 mg/ml)
Topotecan HCl (1 mg/ml)
Trisenox (Arsenic Trioxide) (1 mg/ml)
Vinblastine Sulfate (1 mg/ml)
Vincristine (1 mg/ml)
Vinorelbine Tartrate (10 mg/ml)

The following chemotherapy drugs and concentration showed breakthrough detected in less than 100 minutes:
Carmustine (3.3 mg/ml) No breakthrough up to 44.5 minutes.
Thiotepa (10 mg/ml) No breakthrough up to 99.1 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

The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes:
Chloroquine (50 mg/ml)
Cyclosporin A (100 mg/ml)
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 K243172

This summary of 510(k) K243172 is being submitted in accordance with 21 CFR 807.92.

Date Summary was Prepared	June 18, 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* Powder-Free Exam Gloves, Sterile Pairs; Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Singles
Device Submission Trade name and Description	Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs; Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Singles
Device Common Name	Medical Exam Gloves
Device Product Code and Classification Name	LZA Class I, 21 CFR §880.6250 Polymer 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	Kimberly-Clark Purple Nitrile XTRA* Sterile Powder-Free Exam Glove (Chemotherapy Glove) - 12 Sterile Pairs (K102032)
Reference Devices	Halyard Purple Nitrile, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (K213929)
Subject Device Description	The Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs or Sterile Singles, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid are disposable, 9.5“ purple-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, sterile patient examination gloves.

Indications for Use	Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs or Sterile Singles, 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 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 (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) Carfilzomib (2 mg/ml) Cetuximab (2 mg/ml) Cisplatin (1 mg/ml) Cladribine (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCl (100 mg/ml) Dacarbazine (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 (2 mg/ml) Etoposide (20 mg/ml) Fludarabine Phosphate (25 mg/ml) Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine HCl (38 mg/ml) Idarubicin HCl (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan HCl (20 mg/ml) Leuprolide Acetate (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 (6 mg/ml) Pemetrexed (25 mg/ml) Raltitrexed (0.5 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Topotecan HCl (1 mg/ml)

	Trisenox (Arsenic Trioxide) (1 mg/ml) Vinblastine Sulfate (1 mg/ml) Vincristine (1 mg/ml) Vinorelbine Tartrate (10 mg/ml) The following chemotherapy drugs and concentration showed breakthrough detected in less than 100 minutes: Carmustine (3.3 mg/ml) No breakthrough up to 44.5 minutes. Thiotepa (10 mg/ml) No breakthrough up to 99.1 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 The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Chloroquine (50 mg/ml) Cyclosporin A (100 mg/ml) Cytovene (10 mg/ml) Retrovir (10 mg/ml) Triclosan (2 mg/ml) Zoledronic Acid (0.8 mg/ml)

	Subject Device	Predicate Device (K102032)	Reference Device (K213929)	Comparison
FDA Product Code	LZA, LZC, OPJ, QDO	LZA, LZC	LZA, OPJ, QDO	Similar
FDA Classification	Class I	Class I	Class I	Same
Regulation Number	880.6250	880.6250	880.6250	Same
Common Name	Medical Exam Glove	Medical Exam Glove	Medical Exam Glove	Same
Device Trade Name	Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs; Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Singles	Kimberly-Clark Purple Nitrile XTRA* Sterile Powder-Free Exam Glove (Chemotherapy Glove) - 12 Sterile Pairs	Halyard Purple Nitrile, Powder-Free Exam Gloves 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* Powder-Free Exam Gloves, Sterile Pairs or Sterile Singles, 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 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 (25 mg/ml) Bendamustine HCl (5 mg/ml) Bleomycin Sulfate (15	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05: The following drugs had NO breakthrough detected up to 240 minutes: Bleomycin Sulfate (15 mg/ml) Busulfan (6 mg/ml) Carboplatin (10 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCl (100 mg/ml) Dacarbazine (10 mg/ml) Daunorubicin HCl (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCl (Adriamycin) (2 mg/ml)	Halyard Purple Nitrile* Powder-Free Exam Gloves, 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 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 (25 mg/ml)	Similar

	mg/ml) Bortezomib (1 mg/ml) Busulfan (6 mg/ml) Capecitabine (26 mg/ml) Carboplatin (10 mg/ml) Carfilzomib (2 mg/ml) Cetuximab (2 mg/ml) Cisplatin (1 mg/ml) Cladribine (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCl (100 mg/ml) Dacarbazine (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 (2 mg/ml) Etoposide (20 mg/ml) Fludarabine Phosphate (25 mg/ml) Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine HCl (38 mg/ml) Idarubicin HCl (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan HCl (20 mg/ml) Leuprolide Acetate (5 mg/ml) Mechlorethamine HCl (1 mg/ml) Melphalan HCl (5 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5	Ellence (Epirubicin) (2 mg/ml) Etoposide (20 mg/ml) Fludarabine (25 mg/ml) Fluorouracil (adrucil) (50 mg/ml) Gemcitabine (38.0 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) Fludarabine (25 mg/ml) 5-Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (38 mg/ml)	

	mg/ml) Mitoxantrone HCl (2 mg/ml) Oxaliplatin (5 mg/ml) Paclitaxel (6 mg/ml) Pemetrexed (25 mg/ml) Raltitrexed (0.5 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Topotecan HCl (1 mg/ml) Trisenox (Arsenic Trioxide) (1 mg/ml) Vinblastine Sulfate (1 mg/ml) Vincristine (1 mg/ml) Vinorelbine Tartrate (10 mg/ml) The following chemotherapy drugs and concentration showed breakthrough detected in less than 100 minutes: Carmustine (3.3 mg/ml) No breakthrough up to 44.5 minutes. Thiotepa (10 mg/ml) No breakthrough up to 99.1 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		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	

	Fluid/Fentanyl Citrate Injection Mix 50/50 Solution The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Chloroquine (50 mg/ml) Cyclosporin A (100 mg/ml) Cytovene (10 mg/ml) Retrovir (10 mg/ml) Triclosan (2 mg/ml) Zoledronic Acid (0.8 mg/ml)		55.3 minutes. Thiotepa (10 mg/ml) No breakthrough up to 78.8 minutes. Warning- Not for use with Carmustine and ThioTEPA No breakthrough was detected up to 240 minutes for Fentanyl Citrate Injection (100 mcg/2 ml) and Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution	
Technological Characteristics	Colored, 9.5 inch, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, sterile patient examination glove	Colored, 9.5 inch, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, sterile patient examination glove	Colored, 9.5 inch, chlorinated, nitrile, powder-free, textured fingertips, ambidextrous, non-sterile patient examination glove	Similar
Sizes of gloves	S, M, L	S, M, L	XS, S, M, L, XL	Similar
Color	Purple	Purple	Purple	Similar

Texture	Textured fingertips	Textured fingertips	Textured fingertips	Same
Sterility	Sterile	Sterile	Non-Sterile	Similar
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 ISO 10993 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 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 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 non-sensitizer. Meets the acceptance criteria.	

Standard	Subject Device	Predicate Device (K102032)	Reference Device (K213929)	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 (25 mg/ml)	These chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05: The following drugs had NO breakthrough detected up to 240 minutes: Bleomycin Sulfate (15	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (25	Similar

	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) Carfilzomib (2 mg/ml) Cetuximab (2 mg/ml) Cisplatin (1 mg/ml) Cladribine (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCl (100 mg/ml) Dacarbazine (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 (2 mg/ml) Etoposide (20 mg/ml) Fludarabine Phosphate (25 mg/ml) Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine HCl (38 mg/ml) Idarubicin HCl (1 mg/ml) Ifosfamide (50 mg/ml) Irinotecan HCl (20 mg/ml) Leuprolide Acetate (5 mg/ml) Mechlorethamine HCl (1 mg/ml) Melphalan HCl (5 mg/ml)	mg/ml) Busulfan (6 mg/ml) Carboplatin (10 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (20 mg/ml) Cytarabine HCl (100 mg/ml) Dacarbazine (10 mg/ml) Daunorubicin HCl (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCl (Adriamycin) (2 mg/ml) Ellence (Epirubicin) (2 mg/ml) Etoposide (20 mg/ml) Fludarabine (25 mg/ml) Fluorouracil (adrucil) (50 mg/ml) Gemcitabine (38.0 mg/ml)	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) Fludarabine (25 mg/ml) 5-Fluorouracil (50 mg/ml) Fulvestrant (50 mg/ml) Gemcitabine (38	

	Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone HCl (2 mg/ml) Oxaliplatin (5 mg/ml) Paclitaxel (6 mg/ml) Pemetrexed (25 mg/ml) Raltitrexed (0.5 mg/ml) Rituximab (10 mg/ml) Temsirolimus (25 mg/ml) Topotecan HCl (1 mg/ml) Trisenox (Arsenic Trioxide) (1 mg/ml) Vinblastine Sulfate (1 mg/ml) Vincristine (1 mg/ml) Vinorelbine Tartrate (10 mg/ml) The following chemotherapy drugs and concentration showed breakthrough detected in less than 100 minutes: Carmustine (3.3 mg/ml) No breakthrough up to 44.5 minutes. Thiotepa (10 mg/ml) No breakthrough up to 99.1 minutes. Warning- Not for use with Carmustine and ThioTEPA The following hazardous drugs and concentration had NO breakthrough detected up to 240 minutes: Chloroquine (50 mg/ml) Cyclosporin A (100		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	

	mg/ml) Cytovene (10 mg/ml) Retrovir (10 mg/ml) Triclosan (2 mg/ml) Zoledronic Acid (0.8 mg/ml)		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	
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) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution	Not Previously Tested	No breakthrough was detected up to 240 minutes for Fentanyl Citrate Injection (100 mcg/2 ml) and Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution	Different

ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves	Testing of the subject device shows it meets the 2.5% AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard.	Testing of the 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	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	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	Same

	meets the acceptance criteria for powder-free.	for powder-free	for powder-free.	
ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications	The physical dimensions of the subject device are within the limits of the standard and the physical properties of the subject device met the requirements for tensile strength before and after aging. The subject device also met the requirement for elongation before and after aging.	The physical dimensions of the predicate device are within the limits of 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.	The physical dimensions of the reference device are within the limits of 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.	Same

SUMMARY OF NON-CLINICAL TESTING

Brief description of non-clinical tests:	Test	Standard	Acceptance Criteria	Results
	Dimensions	ASTM D 6319		Meets requirements
		Length	≥230 mm	
		Palm Width Size	Small: 70 - 90 mm Med: 85–105 mm Large: 100 - 120 mm	
		Finger thickness Palm thickness Cuff thickness	≥0.05 mm ≥0.05 mm ≥0.05 mm	

	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
	Sterility	ANSI/AAMI/ISO 11137	10^{-6}	10^{-6}
	Powder Free	ASTM D 6124 ASTM D 6319	≤ 2 mg / glove	Meets requirements
	Test for irritation	ISO 10993, Part 23	Grade 1	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 44.5 minutes

				Thiotepa 10mg/ml minimum breakthrough detection time is 99.1 minutes.

Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject devices (Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs or Sterile Singles) are as safe, as effective, and performs as well as the legally marketed devices cleared under K102032.