December 17, 2024

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

Re: K242558
Trade/Device Name: Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl 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 18, 2024
Received: November 18, 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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K242558

Device Name
Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

Indications for Use *(Describe)*
Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, 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:
Cisplatin, 1 mg/ml
Cyclophosphamide, 20 mg/ml
Dacarbazine, 10 mg/ml
Doxorubicin HCl, 2 mg/ml
Etoposide, 20 mg/ml
Fluorouracil, 50 mg/ml
lfosfamide, 50 mg/ml
Mitoxantrone HCl, 2 mg/ml
Paclitaxel, 6 mg/ml
Vincristine Sulfate, 1 mg/ml

CAUTION: The following chemotherapy drug and concentration showed breakthrough detected in less than 60 minutes:
Carmustine, 3.3 mg/ml: No breakthrough up to 35.1 minutes.

CAUTION: The following chemotherapy drug and concentration showed breakthrough detected in less than 120 minutes:
Thiotepa, 10 mg/ml: No breakthrough up to 107.2 minutes.

Warning: Not for use with Carmustine, Thiotepa

The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes:
Fentanyl Citrate Injection (50 mcg/5 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.

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

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

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

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

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

510(k) Summary for K242558

This summary of 510(k) K242558 is being submitted in accordance with 21 CFR 807.92.

1. Date Summary was Prepared	December 13, 2024
2. 510(k) Submitter	O & M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia 23116
3. Primary Contact for this 510(k) Submission	Caitlin Senter, MS, RAC Tel: 678-221-7330 Email: caitlin.senter@owens-minor.com
4. Marketed Common Name	Nitrile Powder-Free Exam Gloves
5. Device Submission Trade name and Description	Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid
6. Device Common Name	Medical Exam Gloves
7. 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
8. Predicate Device	Get-A-Grip/Rescue-Grip, Nitrile Two Toned Black/Green, Diamond Grip Technology, Powder-Free, Non-sterile, Ambidextrous, Beaded Cuff, Medical Grade Exam Gloves (K220373)
9. 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) Halyard Black-Fire Powder-Free Nitrile Exam Glove, Halyard Purple Powder-Free Nitrile Exam Glove (K200633)

11. Subject Device Description	The subject device is a disposable, 9.5" black-colored, chlorinated, nitrile, powder-free, textured, ambidextrous, non-sterile patient examination glove that is 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 D6319-19 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 10993-10: 2021 Biological evaluation of medical devices -Part 10: Tests for skin sensitization ISO 10993-23: 2021 Biological evaluation of medical devices -Part 23: Tests for irritation

12. Indications for Use for Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid	Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, 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: Cisplatin, 1 mg/ml Cyclophosphamide, 20 mg/ml Dacarbazine, 10 mg/ml Doxorubicin HCl, 2 mg/ml Etoposide, 20 mg/ml Fluorouracil, 50 mg/ml Ifosfamide, 50 mg/ml Mitoxantrone HCl, 2 mg/ml Paclitaxel, 6 mg/ml Vincristine Sulfate, 1 mg/ml CAUTION: The following chemotherapy drug and concentration showed breakthrough detected in less than 60 minutes: Carmustine, 3.3 mg/ml: Do not use CAUTION: The following chemotherapy drug and concentration showed breakthrough detected in less than 120 minutes: Thiotepa, 10 mg/ml: Do not use Warning: Not for use with Carmustine, Thiotepa The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (50 mcg/5 ml) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

13.	Subject Device Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip	Predicate Device K220373	Reference Device K213929	Reference Device K200633	Comparison
FDA Product Code	LZA, LZC, OPJ, QDO	LZA, OPJ, QDO	LZA, OPJ, QDO	LZA, QDO, LZC	Similar
FDA Classification	Class I	Class I	Class I	Class I	Same
Regulation Number	880.6250	880.6250	880.6250	880.6250	Same
Common Name	Non-Powdered Patient Examination Glove	Non-Powdered Patient Examination Glove	Non-Powdered Patient Examination Glove	Non-Powdered Patient Examination Glove	Same
Device Trade Name	Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid	Get-A-Grip/Rescue-Grip, Nitrile Two Toned Black/Green, Diamond Grip Technology, Powder-Free, Non-sterile, Ambidextrous, Beaded Cuff, Medical Grade Exam Gloves	Halyard Purple Nitrile, Powder-Free Exam Gloves	Halyard Black-Fire Powder-Free Nitrile Exam Glove	Similar
Intended Use	The device 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, simulated gastric acid and fentanyl in simulated gastric acid as listed on the label.	A Nitrile powder free exam glove is a disposable device, worn on the hand or finger to prevent contamination between examiner and patient or victim. This specialty glove has also been tested for use with the Opioid drugs Fentanyl citrate, Heroin, and both Opioids in simulated 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, fentanyl citrate, simulated gastric acid fluid/fentanyl citrate injection mix 50/50 Solution 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 fentanyl citrate as listed on the label.	Similar

Technological Characteristics	Colored, 9.5 inch, chlorinated, nitrile, powder-free, textured, ambidextrous, non-sterile patient examination glove	Colored, 9.5 inch, chlorinated, nitrile, powder-free, textured, ambidextrous, non-sterile patient examination glove	Colored, 9.5 inch, chlorinated, nitrile, powder-free, textured fingertip, 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, XXL	XS, S, M, L, XL	XS, S, M, L, XL	Similar
Glove Length	9.5 inch	9.5 inch	12 inch	9.5 inch	Similar
Texture	Textured on dorsal and palmar sides through the fingertips	Textured on dorsal and palmar sides through the fingertips	Textured fingertips	Textured fingertips	Similar
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same

14. Standard	**Subject Device Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip**	**Predicate Device K220373**	**Reference Device K213929**	**Reference Device K200633**	**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: Cisplatin, 1 mg/ml Cyclophosphamide, 20 mg/ml Dacarbazine, 10 mg/ml Doxorubicin HCl, 2 mg/ml Etoposide, 20 mg/ml Fluorouracil, 50 mg/ml Ifosfamide, 50 mg/ml Mitoxantrone HCl, 2 mg/ml Paclitaxel, 6 mg/ml Vincristine Sulfate, 1 mg/ml CAUTION: The	This specialty glove has also been tested for use with the Opioid drugs Fentanyl citrate, Heroin, and both Opioids in simulated Gastric Acid. Test Opioid Drug / Concentration / Minimum Breakthrough Time Fentanyl citrate (injectable) / [100mcg/2mL) / >240 minutes Fentanyl citrate (injectable) + Heroin / [100mcg/2mL) + (saturated solution) / >240 minutes Fentanyl citrate (injectable) + Heroin in Simulated Gastric Acid Mix / 100mcg/2mL Saturated Solution into simulated Gastric Acid / >240 minutes	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	The following drugs showed not breakthrough at 240 minutes: Fentanyl Citrate, 100 mcg/2ml	Similar

	following chemotherapy drug and concentration showed breakthrough detected in less than 60 minutes: Carmustine, 3.3 mg/ml: Do not use CAUTION: The following chemotherapy drug and concentration showed breakthrough detected in less than 120 minutes: Thiotepa, 10 mg/ml: Do not use Warning: Not for use with Carmustine, Thiotepa The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (50 mcg/5 ml) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution		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) 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 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		
Biocompatibility Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer.	Under the conditions of the study, not a sensitizer. Under the conditions of the study, not an irritant.	Under the conditions of the study, not a sensitizer. Under the conditions of the study, not an	Under the conditions of the study, not a sensitizer. Under the	Same

			irritant.	conditions of the study, not an irritant.	
Biocompatibility Cytotoxicity ISO 10993-5	Not Performed	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by acute systematic toxicity testing.	Not Performed	Not Performed	Different from K220373 Same as K200633 and K213929
Biocompatibility Acute Systemic Toxicity ISO 10993-11	Under the conditions of the study, the device extract does not induce acute systemic toxicity response.	Under the conditions of this study, there was no evidence of acute systemic toxicity.	Under the conditions of this study, there was no evidence of acute systemic toxicity.	Under the conditions of this study, there was no evidence of acute systemic toxicity.	Same
Biocompatibility Irritation ISO 10993-23	Under the conditions of the study, not an irritant.	Not Performed	Not Performed	Not Performed	Different

15. SUMMARY OF NON-CLINICAL TESTING

Biocompatibility

Biocompatibility Testing according to ISO 10993-1:2018, the nature of body contact for the proposed device is Surface Device and duration of contact is A-Limited (≤24h). The following tests for the proposed device were conducted to evaluate the biocompatibility of Nitrile Disposable Examination Gloves as per Guidance for Industry and FDA Staff-Medical Guidance Manual issued on January 22, 2008.

- ISO 10993-23: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-11: Systemic Toxicity

Performance Testing

Physical Performance testing of the proposed device were conducted as per ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application*. Permeation testing was conducted to support the addition of the labeling claim. Tested for use with chemotherapy drugs. In addition, the proposed device was tested according to ASTM D6978-05 (2023) *Standard Practice for Assessment of resistance of Medical Gloves to Permeation by Chemotherapy Drugs*, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs and fentanyl citrate.

To summarize, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance to the relevant test methods cited below:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6978-05 Standard Practice for Assessment of resistance of Medical Gloves to Permeation by Chemotherapy Drugs

For the test result, we can find the product can meet the requirements as its intended use indicated.

Test Method	Standard	Acceptance Criteria	Results
Dimensions (Length) (Width) (Thickness)	ASTM D6319 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	PASS
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%	PASS
Freedom from Pinholes	ASTM D 6319 ASTM D 5151	AQL 2.5% No leakage	PASS
Residual Powder	ASTM D 6124 ASTM D 6319	≤ 2 mg / glove	PASS
Permeation by Chemotherapy Drugs	ASTM D6978	Refer to the above table	PASS
Test for irritation	ISO 10993, Part 23	No dermal irritation reactions	PASS
Test for acute systemic toxicity	ISO 10993, Part 11	Under the conditions of the study, the device extract does not induce acute systemic toxicity response.	PASS
Test for skin sensitization	ISO 10993, Part 10	No dermal reactions indicative of delayed contact hypersensitivity.	PASS

16. CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

17. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in K242558, Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K220373.