March 13, 2020

O & M Halyard, Inc.
Steven Dowdley
Associate Director of Regulatory Affairs
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K192241
Trade/Device Name: Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: February 10, 2020
Received: February 12, 2020

Dear Steven Dowdley:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved OMB No 0910-0120
Expiration Date 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K192241

Device Name

The Halyard Purple Xtra Sterile and Purple Sterile, Low Dermatitis Potential Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*

The Halyard Purple Xtra Sterile and Purple Sterile, Low Dermatitis Potential Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrateis are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with the following chemotherapy drugs and Fentanyl Citrate as per ASTM -D6978-05 :

Arsenic Trioxide (1 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 breakthrough up to 240 minutes
Cisplatin (1 mg/ml) No breakthrough up to 240 minutes
Cladribine (1 0 mg/ml) No breakthrough up to 240 minutes
Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes
Cytarabine 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 (10 mg/ml) No breakthrough up to 240 minutes
Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes
Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes
Etoposide (20 mg/ml) No breakthrough up to 240 minutes
Fludarabine (25 mg/ml) No breakthrough up to 240 minutes
Fluorouracil (50 mg/ml) No breakthrough up 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
Irinotecan (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
Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes
Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes
Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes
Paraplatin (10 mg/ml) No breakthrough up to 240 minutes
Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes

Pertuzumab (30 mg/ml) No breakthrough up to 240 minutes
Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes
Retrovir (10 mg/ml) No breakthrough up to 240 minutes
Rituximab (10 mg/ml) No breakthrough up to 240 minutes
Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes
Trastuzumab (21 mg/ml) No breakthrough up to 240 minutes
ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes
Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes
Triclosan (1 mg/ml) No breakthrough up to 240 minutes
Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes
Vincristine Sulfate (1 mg/ml) No breakthrough up to 240 minutes
Vinblastine (1 mg/ml) No breakthrough up to 240 minutes
Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes
Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes

Fentanyl Citrate (100mcg/2ml) No breakthrough up to 240 minutes

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K192241

Date Summary was Prepared	March 12, 2020
510(k) Submitter	O & M Halyard, Inc. 5405 Windward Parkway Alpharetta, GA 30004
Primary Contact for this 510(k) Submission	Steven Dowdley, RAC Tel: 678-451-8062 Email: steven.dowdley@hyh.com
Device Trade Name	Halyard Purple Xtra Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate Halyard Purple Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Device Common Name	Medical Exam Gloves
Device Product Code and Classification Name	LZA Class I, 21 CFR §880.6250 Patient Examination Glove
Subsequent Product Codes	LZC Class I, 21 CFR §880.6250 Patient Examination Glove, Specialty QDO Class I, 21 CFR §880.6250 Fentanyl and other opioid protection glove
Predicate Device	K102032 KIMBERLY-CLARK PURPLE NITRILE XTRA* STERILE POWDER-FREE EXAM GLOVE (CHEMOTHERAPY GLOVE)
Subject Device Description	Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are disposable, purple-colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, sterile patient examination gloves. 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 - Part 11: Tests for Systemic Toxicity • ISO 10993-10: 2010: Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization

Indications for Use	The Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with the following chemotherapy drugs and Fentanyl Citrate as per ASTM -D6978-05: Arsenic Trioxide (1 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 breakthrough up to 240 minutes Cisplatin (1 mg/ml) No breakthrough up to 240 minutes Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes Cytarabine 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 (10 mg/ml) No breakthrough up to 240 minutes Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes Etoposide (20 mg/ml) No breakthrough up to 240 minutes Fludarabine (25 mg/ml) No breakthrough up to 240 minutes Fluorouracil (50 mg/ml) No breakthrough up 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 Irinotecan (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 Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes Paraplatin (10 mg/ml) No breakthrough up to 240 minutes Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes Pertuzumab (30 mg/ml) No breakthrough up to 240 minutes Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes Retrovir (10 mg/ml) No breakthrough up to 240 minutes Rituximab (10 mg/ml) No breakthrough up to 240 minutes Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes Trastuzumab (21 mg/ml) No breakthrough up to 240 minutes ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes Triclosan (1 mg/ml) No breakthrough up to 240 minutes Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes Vincrinstine Sulfate (1 mg/ml) No breakthrough up to 240 minutes Vinblastine (1 mg/ml) No breakthrough up to 240 minutes Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes Fentanyl Citrate (100mcg/2ml) No breakthrough up to 240 minutes.

Technological Characteristics Comparison Table

	Subject Device K192241	Predicate Device K102032	Comparison
FDA Product Code	LZA, LZC, QDO	LZC, LZA	Same
FDA Classification	Class I	Class I	Same
Regulation Number	880.6250	880.6250	Same
Common Name	Medical Exam Glove	Medical Exam Glove	Same
Device Trade Name	Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Kimberly Clark Purple Xtra and Purple Sterile, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs	Same
Intended Use	The Halyard Purple Xtra and Purple Sterile, Low Dermtatis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrates are 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 listed on the label.	Kimberly Clark Purple Xtra and Purple Sterile, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs are 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 listed on the label.	Different
Technological Characteristics	The glove is a colored, nitrile, powder-free, textured fingertip, ambidextrous, patient examination glove.	The glove is a colored, nitrile, powder-free, textured fingertip, ambidextrous, patient examination glove.	Same
Sizes of gloves	XS, S, M, L, XL	XS, S, M, L, XL	Same

Texture	Textured fingertips	Textured fingertips	Same
Sterility	Sterile	Sterile	Same
Biocompatibility	Based ISO 10993 Biological evaluation of Medical devices – Test for Systemic Injection, the test article was considered non-toxic. Meets the acceptance criteria.	Based ISO 10993 Biological evaluation of Medical devices – Test for Systemic Injection, the test article was considered non-toxic. Meets the acceptance criteria.	Same
	Based on ISO 10993-Biological evaluation of Medical Devices – Test for Skin Irritation, the device extracts were not found to cause a systemic response in the animal model. Meets the acceptance criteria.	Based on ISO 10993-Biological evaluation of Medical Devices – Test for Skin Irritation, the device extracts were not found to cause a systemic response in the animal model. Meets the acceptance criteria.	

Performance Data for Chemotherapy Drugs			
Standard	**Results** **Subject Devices**	**Results** **Predicate Devices K102032**	**Remarks**
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Arsenic Trioxide (1 mg/ml) No breakthrough up to 240 minutes 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 breakthrough up to 240 minutes Cisplatin (1 mg/ml) No breakthrough up to 240 minutes Cladribine (1.0 mg/ml) No breakthrough up to 240 minutes Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes Cytarabine 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 (10 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 Carmustine (3.3 mg/ml) permeation occurred at 48.6 minutes Cyclophosphamide (20 mg/ml) No breakthrough up to 240 minutes Cytarabine HCL (100 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 Docetaxel (10 mg/ml) No breakthrough up to 240 minutes Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes Etoposide (20 mg/ml) No breakthrough up to 240 minutes Fludarabine (25 mg/ml) No breakthrough up to 240 minutes Fluorouracil (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 Irinotecan (20 mg/ml) No breakthrough up to 240 minutes Mechlorethamine HCL (1 mg/ml) No breakthrough up to 240 minutes	Similar

	Doxorubicin HCL (2 mg/ml) No breakthrough up to 240 minutes Epirubicin (Ellence) (2 mg/ml) No breakthrough up to 240 minutes Etoposide (20 mg/ml) No breakthrough up to 240 minutes Fludarabine (25 mg/ml) No breakthrough up to 240 minutes Fluorouracil (50 mg/ml) No breakthrough up 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 Irinotecan (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 Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes Oxaliplatin (2 mg/ml) No breakthrough up to 240 minutes Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes Paraplatin (10 mg/ml) No breakthrough up to 240 minutes Pemetrexed (25 mg/ml) No breakthrough up to 240 minutes Pertuzumab (30 mg/ml) No breakthrough up to 240 minutes Raltitrexed (0.5 mg/ml) No breakthrough up to 240 minutes Retrovir (10 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 (0.5 mg/ml) No breakthrough up to 240 minutes Mitoxantrone (2 mg/ml) No breakthrough up to 240 minutes Paclitaxel (6 mg/ml) No breakthrough up to 240 minutes Paraplatin (10 mg/ml) No breakthrough up to 240 minutes Rituximab (10 mg/ml) No breakthrough up to 240 minutes ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes Vincrinstine Sulfate (1 mg/ml) No breakthrough up to 240 minutes	

	Rituximab (10 mg/ml) No breakthrough up to 240 minutes Temsirolimus (25 mg/ml) No breakthrough up to 240 minutes Trastuzumab (21 mg/ml) No breakthrough up to 240 minutes ThioTEPA (10 mg/ml) No breakthrough up to 240 minutes Topotecan HCL (1 mg/ml) No breakthrough up to 240 minutes Triclosan (1 mg/ml) No breakthrough up to 240 minutes Trisenox (0.1 mg/ml) No breakthrough up to 240 minutes Vincrinstine Sulfate (1 mg/ml) No breakthrough up to 240 minutes Vinblastine (1 mg/ml) No breakthrough up to 240 minutes Vinorelbine (10 mg/ml) No breakthrough up to 240 minutes Zoledronic Acid (0.8 mg/ml) No breakthrough up to 240 minutes		

Performance Data for Fentanyl Citrate Injection			
Standard	**Results** **Subject Devices**	**Results** **Predicate Devices K102032**	**Remarks**
ASTM D 6978	Fentanyl Citrate Injection, (100mcg /2mL). No breakthrough up to 240 minutes	Not tested	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 subject 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 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.	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 subject device also met the requirement for elongation before and after aging.	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.	Same
ISO 10993 Biological evaluation of medical devices	Meets acceptance criteria	Meets acceptance criteria	Same

Non- Clinical Testing Summary

PERFORMANCE CHARACTERISTICS OF THE SUBJECT DEVICE:

Brief description of non-clinical tests:	Test	Standard	Acceptance Criteria	Results
	Dimensions	ASTM D 6319	Length ≥ 230mm Palm width Size Xtra-Small: 60 – 80 mm Small: 70 - 90 mm Medium: 85 – 105 mm Large: 100 - 120 mm Xtra-Large: 110-130 mm Finger Thickness ≥0.050 mm Palm Thickness ≥0.050 mm Cuff Thickness 0.10-0.13 mm (Halyard)	The physical dimensions of the subject device are within the limits of the standard.
	Physical Properties	ASTM D 6319	AQL 4.0 Before Tensile Strength: ≥14 MPa Ultimate elongation: ≥500% After Tensile Strength: ≥14 MPa Ultimate elongation: ≥400%	Physical properties of the subject device meet the requirements for tensile strength and elongation in the standard.
	Freedom from Pinholes	ASTM D 6319 ASTM D 5151	AQL 2.5% No leakage	Testing of the subject device shows it meets the AQL requirement in the standards for leakage.

	Powder-Free	ASTM D 6124 ASTM D 6319	≤ 2 mg / glove	Residual powder on the subject device is within the powder-free limits prescribed in the standards.
	ISO Indirect Irritation Study	ISO 10993, Part 10	Primary Irritation Index ≤ 2.0	Under the conditions of the study the device is not an irritant.
	ISO Systemic Toxicity Study	ISO 10993, Part 11	No animals treated with test extracts exhibit greater reaction than control animals	No evidence of systemic toxicity.
	ISO Dermal Sensitization	ISO 10993, Part 10	Grade < 1	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 was detected for up to 240 minutes	Acceptance criteria: No signs of breakthrough for the subject device after 4 hours for 51 chemotherapy drugs. Carmustine showed no signs of breakthrough until 169.8 minutes. No signs of breakthrough after 4 hours for Fentanyl Citrate Injection (100 mcg/2ml)
Brief description of clinical tests:	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			
Conclusions:	The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject devices (the Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate) are as safe, as effective, and performs as well as or better than the legally marketed devices cleared under K102032.			