October 11, 2020

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

Re: K200633
Trade/Device Name: Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate; Halyard Purple Nitrile Powder-Free Exam Glove 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, QDO, LZC
Dated: September 8, 2020
Received: September 10, 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,

For: CAPT 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)*
K200633

Device Name
Halyard Black Fire Powder-Free Nitrile Exam Glove tested with Fentanyl Citrate

Indications for Use *(Describe)*
The Halyard Black Fire Powder-Free Nitrile Exam Glove tested with Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The following drugs showed not breakthrough at 240 minutes:

Fentanyl Citrate, 100 mcg/2ml

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."

Indications for Use

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

510(k) Number *(if known)*
K200633

Device Name
Halyard Purple Nitrile Powder-Free Exam Glove tested with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
The Halyard Purple Nitrile Powder-Free Exam Glove tested with Chemotherapy Drugs and Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The following drugs showed not breakthrough at 240 minutes:
Bleomycin (15.0 mg/ml)
Busulfan (6.0 mg/ml)
Carboplatin (10.0 mg/ml)
Cisplatin (1.0 mg/ml)
Cyclophosphamide (20.0 mg/ml)
Cytarabine (100.0 mg/ml)
Dacarbazine (DTIC) (10.0 mg/ml)
Daunorubicin (5.0 mg/ml)
Docetaxel (10.0 mg/ml)
Doxorubicin Hydrochloride (2.0 mg/ml)
Ellence (2.0 mg/ml)
Etoposide (Toposar) (20.0 mg/ml)
Fludarabine (25.0 mg/ml)
Fluorouracil (50.0 mg/ml)
Gemcitabine (Gemzar) (38.0 mg/ml)
Idarubicin (1.0 mg/ml)
Ifosfamide (50.0 mg/ml)
Irinotecan (20.0 mg/ml)
Mechlorethamine HCl (1.0 mg/ml)
Melphalan (5.0 mg/ml)
Methotrexate (25.0 mg/ml)
Mitomycin C (0.5 mg/ml)
Mitoxantrone (2.0 mg/ml)
Paclitaxel (Taxol) (6.0 mg/ml)
Paraplatin (10.0 mg/ml)
Rituximab (10.0 mg/ml)
Trisonex (1.0 mg/ml)
Vincrinstine (1mg/ml)

Fentanyl Citrate, 100 mcg/2ml

The following drugs showed breakthrough detected in less than 30 minutes: Carmustine (3.3mg/ml) 1.8 minutes and ThioTEPA (10.0mg/ml): 1.7 minutes.

Warning- Not for use with Carmustine and ThioTEPA.

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

K200633

Date Summary was Prepared:	October 10, 2020
510(k) Submitter:	Steven Dowdley Associate Director, Regulatory Affairs 505 Windward Parkway Alpharetta, GA 30004 Email: steven.dowdley@hyh.com Phone: 678-451-8062
Primary Contact for this 510(k):	Same as above
Device1 Trade Name:	Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate
Device2 Trade Name:	Halyard Purple Nitrile Powder-Free Exam Glove tested for use with Chemotherapy Drugs and Fentanyl Citrate
Common Name:	Powder Free Nitrile Patient Examination Glove
Device1 Product Code:	LZA, QDO
Device2 Product Code:	LZC, QDO
Classification:	Class I
Regulation:	21 CFR §880.6250
Predicate Device1:	K153708 Halyard Black-Orange Powder-Free Nitrile Exam Glove
Predicate Device2:	K101596 Kimberly-Clark PURPLE NITRILE Powder-Free Exam Glove with Tested for Use with Chemotherapy Drugs

DEVICE DESCRIPTION

The Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate is a disposable, black-colored on the grip side and orange colored on the donning side, nitrile, powder- free, textured fingertip, ambidextrous, non-sterile patient examination glove that are chlorinated on the donning side and are packed in a cardboard dispenser box.

The Halyard Purple Nitrile Powder-Free Exam Glove tested for use with Chemotherapy Drugs and Fentanyl Citrate is a disposable, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves that are chlorinated on the donning side and are packed in a cardboard dispenser box.

INTENDED USE

The Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The Halyard Purple Nitrile Powder-Free Exam Glove tested for use with Chemotherapy Drugs and Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 1 comparison between the predicate Device 1 and subject Device 1

	Subject Device1 K200633	Predicate Device1 K153708	Remarks
Product Code	LZA, QDO	LZA	Different
Classification	Class 1	Class 1	Same
Trade Name	Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate	Halyard Black-Orange Powder-Free Nitrile Exam Glove	Similar
Indications for Use	The Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The following drugs showed no breakthrough at 240 minutes: Fentanyl Citrate, 100 cg/2ml	The Halyard® Black-Orange Powder-Free Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Similar
Technological Characteristics	Black on the grip side, orange on the donning side, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	Black on the grip side, orange on the donning side, nitrile, powder-free, textured fingertip, ambidextrous, non- sterile patient examination glove.	Same
Sterilization	Gloves are supplied non-sterile	Gloves are supplied non-sterile	Same
ISO 10993-10 Biological evaluation of medical devices - Tests for Irritation	Acceptance criteria: No erythema/edema up to 72 hours post exposure. Result: Erythema/edema was negligible. Meets acceptance criteria. PASS	Acceptance criteria: No erythema/edema up to 72 hours post exposure. Result: Erythema/edema was negligible. Meets acceptance criteria. PASS	Same
ISO 10993-10 Biological evaluation of medical devices -Tests for Skin Sensitization	Acceptance criteria: No evidence of delayed dermal contact sensitivity at 24 and 48 hours post injection. Result: Not a sensitizer under conditions of the study. Meets acceptance criteria. PASS	Acceptance criteria: No evidence of delayed dermal contact sensitivity at 24 and 48 hours post injection. Result: Not a sensitizer under conditions of the study. Meets acceptance criteria. PASS	Same
ISO 10993 Biological evaluation of medical devices – Tests for Systemic Toxicity	Acceptance criteria: No signs of systemic toxicity up to 72 hours post injection. Result: No systemic toxicity observed. Meets acceptance criteria. PASS	Acceptance criteria: No signs of systemic toxicity up to 72 hours post injection. Result: No systemic toxicity observed. Meets acceptance criteria. PASS	Same

Table 2 comparison between the predicate Device2 and subject Device2

	Subject Device2 K200633	Predicate Device2 K101596	Remarks
Product Code	LZC, QDO	LZC	Different
Classification	Class 1	Class 1	Same
Trade Name	Halyard Purple Nitrile Powder-Free Exam Glove tested for use with Chemotherapy Drugs and Fentanyl Citrate	Kimberly-Clark PURPLE Nitrile Powder-Free Exam Glove with Tested for Use with Chemotherapy Drugs Labeling Claim	Similar
Indications for Use	Halyard Purple Nitrile Powder-Free Exam Glove tested for use with	A powder-free patient examination glove is a disposable device intended for	Similar

	Chemotherapy Drugs and Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The following drugs showed no breakthrough at 240 minutes: Fentanyl Citrate, 100 cg/2ml Bleomycin (15.0 mg/ml) Busulfan (6.0 mg/ml) Carboplatin (10.0 mg/ml) Cisplatin (1.0 mg/ml) Cyclophosphamide (20.0 mg/ml) Cytarabine (100.0 mg/ml) Dacarbazine (DTIC) (10.0 mg/ml) Daunorubicin (5.0 mg/ml) Docetaxel (10.0 mg/ml) Doxorubicin Hydrochloride (2.0 mg/ml) Ellence (2.0 mg/ml) Etoposide (Toposar) (20.0 mg/ml) Fludarabine (25.0 mg/ml) Fluorouracil (50.0 mg/ml) Gemcitabine (Gemzar) (38.0mg/ml) Idarubicin (1.0 mg/ml) Ifosfamide (50.0 mg/ml) Irinotecan (20.0 mg/ml) Mechlorethamine HCl (1.0 mg/ml) Melphalan (5.0 mg/ml) Methotrexate (25.0mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2.0mg/ml) Paclitaxel (Taxol) (6.0 mg/ml) Paraplatin (10.0 mg/ml) Rituximab (10.0 mg/ml) Trisonex (1.0 mg/ml) Vincrinstine (1mg/ml) The following drugs showed breakthrough detected in less than 30 minutes: Carmustine (3.3mg/ml): 1.8 minutes ThioTEPA(10.0mg/ml) 1.7 minutes	medical purposes that is worn on the examiners 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 ASTMV D6978-05: The following drugs had no breakthrough detected up to 240 minutes: Bleomycin (15.0 mg/ml) Busulfan (6.0 mg/ml) Carboplatin (10.0 mg/ml) Cisplatin (1.0 mg/ml) Cyclophosphamide (20.0 mg/ml) Cytarabine (100.0 mg/ml) Dacarbazine (DTIC) (10.0 mg/ml) Daunorubicin (5.0 mg/ml) Docetaxel (10.0 mg/ml) Doxorubicin Hydrochloride (2.0 mg/ml) Ellence (2.0 mg/ml) Etoposide (Toposar) (20.0 mg/ml) Fludarabine (25.0 mg/ml) Fluorouracil (50.0 mg/ml) Gemcitabine (Gemzar) (38.0mg/ml) Idarubicin (1.0 mg/ml) Ifosfamide (50.0 mg/ml) Irinotecan (20.0 mg/ml) Mechlorethamine HCl (1.0 mg/ml) Melphalan (5.0 mg/ml) Methotrexate (25.0mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2.0mg/ml) Paclitaxel (Taxol) (6.0 mg/ml) Paraplatin (10.0 mg/ml) Rituximab (10.0 mg/ml) Trisonex (1.0 mg/ml) Vincrinstine (1mg/ml) The following drugs showed breakthrough detected in less than 30 minutes: Carmustine (3.3mg/ml): 1.8 minutes ThioTEPA(10.0mg/ml) 1.7 minutes	
Technological Characteristics	Purple nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination glove.	Purple nitrile, powder- free, textured fingertip, ambidextrous, non-sterile patient examination glove.	Similar
Sterilization	Gloves are supplied non- sterile	Gloves are supplied non- sterile	Same
ISO 10993-10 Biological evaluation of medical devices - Tests for Irritation	Acceptance criteria: No erythema/edema up to 72 hours post exposure. Result: Erythema/edema was negligible. Meets acceptance criteria. PASS	Acceptance criteria: No erythema/edema up to 72 hours post exposure. Result: Erythema/edema was negligible. Meets acceptance criteria. PASS	Same

ISO 10993-10 Biological evaluation of medical devices -Tests for Skin Sensitization	Acceptance criteria: No evidence of delayed dermal contact sensitivity at 24 and 48 hours post injection. Result: Not a sensitizer under conditions of the study. Meets acceptance criteria. PASS	Acceptance criteria: No evidence of delayed dermal contact sensitivity at 24 and 48 hours post injection. Result: Not a sensitizer under conditions of the study. Meets acceptance criteria. PASS	Same
ISO 10993 Biological evaluation of medical devices – Tests for Systemic Toxicity	Acceptance criteria: No signs of systemic toxicity up to 72 hours post injection. Result: No systemic toxicity observed. Meets acceptance criteria. PASS	Acceptance criteria: No signs of systemic toxicity up to 72 hours post injection. Result: No systemic toxicity observed. Meets acceptance criteria. PASS	Same

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Subject Device1, Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate and subject Device2, Halyard Purple Nitrile Powder-Free Exam Glove tested for use with Chemotherapy Drugs and Fentanyl Citrate were both tested for conformance to the applicable sections of the following 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 D 6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 10993-10 Biological evaluation of medical devices -Tests for Irritation and Skin Sensitization
- ISO 10993-11 Biological evaluation of medical devices - Tests for Systemic Toxicity.

Table 3. Non-clinical performance testing for the subject Device1 compared to Predicate device 1

Performance	K200633 Subject Device1 The Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate			K153708 Predicate Device1 Halyard Black-Orange Powder-Free Nitrile Exam Glove			Remarks
ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves	device shows it meets the 2.5 AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard. PASS			device shows it meets the 2.5 AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard. PASS			Same
ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Applications	Properties	Test results	ASTM SPEC	Properties	Test results	ASTM SPEC	Same
	Holes	AQL 1.0%	AQL 2.5%	Holes	AQL 1.0%	AQL 2.5%	
	Length	230-258mm	>230mm	Length	230-258mm	>230mm	
	Width	85-105mm	85-105mm	Width	85-105mm	85-105mm	
	Palm	.05-07mm	>.050mm	Palm	.05-.07mm	>.050mm	
	Unaged Tensile	>16MPa	>14MPa	Unaged Tensile	>16MPa	>14MPa	
	Unaged Elongation	> 500%	> 500%	Unaged Elongation	> 500%	> 500%	
	Aged Tensile	>15MPa	>14MPa	Aged Tensile	>15MPa	>14MPa	
	Aged Elongation	>450%	>400%	Aged Elongation	>450%	>400%	
	Powder	<2mg/glove	<2mg/glove	Powder	<2mg/glove	<2mg/glove	
ASTM D 6978 Standard Practice for Assessment of Resistance of Medical Gloves to	The following drugs showed no breakthrough at 240 minutes: Fentanyl Citrate, 100 mcg/2ml			Not applicable			Different, adding Fentanyl Citrate

Permeation by Chemotherapy Drugs			
ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves	Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free. PASS	Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free. PASS	Same

Table 4. Non-clinical Performance testing for the subject Device2 compared to Predicate device 2

Performance	K200633 Subject Device2 Halyard Purple Nitrile Powder-Free Exam Glove tested for use with Chemotherapy Drugs and Fentanyl Citrate			K101596 Predicate Device2 Kimberly-Clark PURPLE Nitrile Powder-Free Exam Glove with Tested for Use with Chemotherapy Drugs Labeling Claim			Remarks
ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves	device shows it meets the 2.5 AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard. PASS			device shows it meets the 2.5 AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard. PASS			Same
ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Applications	Properties	Test results	ASTM SPEC	Properties	Test results	ASTM SPEC	Same
	Holes	AQL 1.0%	AQL 2.5%	Holes	AQL 1.0%	AQL 2.5%	
	Length	230-258mm	>230mm	Length	230-258mm	>230mm	
	Width	85-105mm	85-105mm	Width	85-105mm	85-105mm	
	Palm	.05-.07mm	>.050mm	Palm	.05-.07mm	>.050mm	
	Unaged Tensile	>16MPa	>14MPa	Unaged Tensile	>16MPa	>14MPa	
	Unaged Elongation	> 500%	> 500%	Unaged Elongation	> 500%	> 500%	
	Aged Tensile	>15MPa	>14MPa	Aged Tensile	>15Ma	>14MPa	
	Aged Elongation	>450%	>400%	Aged Elongation	>450%	>400%	
	Powder	<2mg/glove	<2mg/glove	Powder	<2mg/glove	<2mg/glove	
ASTM D 6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	The following drugs showed no breakthrough at 240 minutes: Fentanyl Citrate, 100 cg/2ml Bleomycin (15.0 mg/ml) Busulfan (6.0 mg/ml) Carboplatin (10.0 mg/ml) Cisplatin (1.0 mg/ml) Cyclophosphamide (20.0 mg/ml) Cytarabine (100.0 mg/ml) Dacarbazine (DTIC) (10.0 mg/ml) Daunorubicin (5.0 mg/ml) Docetaxel (10.0 mg/ml) Doxorubicin Hydrochloride (2.0 mg/ml) Ellence (2.0 mg/ml) Etoposide (Toposar) (20.0 mg/ml) Fludarabine (25.0 mg/ml) Fluorouracil (50.0 mg/ml) Gemcitabine			The following drugs showed no breakthrough at 240 minutes: Bleomycin (15.0 mg/ml) Busulfan (6.0 mg/ml) Carboplatin (10.0 mg/ml) Cisplatin (1.0 mg/ml) Cyclophosphamide (20.0 mg/ml) Cytarabine (100.0 mg/ml) Dacarbazine (DTIC) (10.0 mg/ml) Daunorubicin (5.0 mg/ml) Docetaxel (10.0 mg/ml) Doxorubicin Hydrochloride (2.0 mg/ml) Ellence (2.0 mg/ml) Etoposide (Toposar) (20.0 mg/ml) Fludarabine (25.0 mg/ml) Fluorouracil (50.0 mg/ml) Gemcitabine (Gemzar) (38.0 mg/ml) Idarubicin (1.0 mg/ml)			Similar, adding Fentanyl Citrate

	(Gemzar) (38.0mg/ml) Idarubicin (1.0 mg/ml) Ifosfamide (50.0 mg/ml) Irinotecan (20.0 mg/ml) Mechlorethamine HCl (1.0 mg/ml) Melphalan (5.0 mg/ml) Methotrexate (25.0mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2.0mg/ml) Paclitaxel (Taxol) (6.0 mg/ml) Paraplatin (10.0 mg/ml) Rituximab (10.0 mg/ml) Trisonex (1.0 mg/ml) Vincrinstine (1mg/ml)	Ifosfamide (50.0 mg/ml) Irinotecan (20.0 mg/ml) Mechlorethamine HCl (1.0 mg/ml) Melphalan (5.0 mg/ml) Methotrexate (25.0 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2.0mg/ml) Paclitaxel (Taxol) (6.0mg/ml) Paraplatin (10.0 mg/ml) Rituximab (10.0 mg/ml) Trisonex (1.0 mg/ml) Vincrinstine (1mg/ml)	
ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves	Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free. PASS	Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free. PASS	Same

CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject Device1 in 510(K) submission K200633, the Halyard Black-Fire Powder-Free Nitrile Exam Glove tested for use with Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153708;

The conclusion drawn from the nonclinical tests demonstrates that the subject Device2 in 510(K) submission K200633, Halyard Purple Nitrile Powder-Free Exam Glove tested for use with Chemotherapy Drugs and Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K101596.