January 7, 2021

O & M Halyard, Inc.
Steven Dowdley
Associate Director
1 Edison Drive
Alpharetta, Georgia 30005

Re: K202622
Trade/Device Name: Halyard Lavender, 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,
Product Code: LZC, LZA, QDO
Dated: December 4, 2020
Received: December 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: Elizabeth F. Claverie-Williams, MS
Acting 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

Indications for Use

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

510(k) Number *(if known)*
K202622

Device Name
Halyard Lavender Nitrile, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
The Halyard Lavender Nitrile, 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 :

The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes:
Azacitidine (25 mg/ml)
Bendamustine HCl (5 mg/ml)
Bleomycin Sulfate (15 mg/ml)
Bortezomib (1 mg/ml)
Busulfan (6 mg/ml)
Capecitabine (26 mg/ml)
Carboplatin (10 mg/ml)
Carlzomib (2 mg/ml)
Cetuximab (2 mg/ml)
Chloroquine (50 mg/ml)
Cisplatin (1 mg/ml)
Cladribine (1 mg/ml)
Cyclophosphamide (20 mg/ml)
Cyclosporin A (100 mg/ml)
Cytarabine (Cytosine) (100 mg/ml)
Cytovene (Ganciclovir) (10 mg/ml)
Dacarbazine (DTIC) (10 mg/ml)
Dactinomycin (0.5 mg/ml)
Daunorubicin HCl (5 mg/ml)
Decitabine (5 mg/ml)
Docetaxel (10 mg/ml)
Doxorubicin HCl (2 mg/ml)
Epirubicin HCl (Ellence) (2 mg/ml)
Etoposide (Toposar) (20 mg/ml)
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 60 minutes:
Carmustine (3.3 mg/ml) No breakthrough up to 0.3 minutes.
Thiotepa (10 mg/ml) No breakthrough up to 30.9 minutes.

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

Warning: Not for Use With: Carmustine, 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 for K202622 Halyard Lavender Nitrile, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Date Summary was Prepared	December 4, 2020
510(k) Submitter	O & M Halyard, Inc. 1 Edison Drive Alpharetta, GA 30005
Primary Contact for this 510(k) Submission	Steven Dowdley, RAC Tel: 678-451-8062 Email: steven.dowdley@hyh.com
Marketed Common Name	Halyard Lavender Nitrile Powder-Free Exam Gloves
Device Submission Trade Name and Description	Halyard Lavender Nitrile, Powder-Free Exam Gloves Tested for Use
Device Common Name	Medical Exam Gloves
Device Product Code and Classification Name	LZA Class I, 21 CFR §880.6250 Patient Examination Glove LZC Class I, 21 CFR §880.6250 Patient Examination Glove, Specialty; QDO Class I, 21 CFR §880.6250 Fentanyl and other opioid protection glove
Predicate Device	Halyard Lavender, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs (K180646)
Subject Device Description	Halyard Lavender Nitrile, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are disposable, lavender colored, chlorinated, nitrile, powder-free, textured fingertip, ambidextrous, 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 Lavender Nitrile, 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 : The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Azacitidine (25 mg/ml) Bendamustine HCl (5 mg/ml) Bleomycin Sulfate (15 mg/ml) Bortezomib (1 mg/ml) Busulfan (6 mg/ml) Capecitabine (26 mg/ml) Carboplatin (10 mg/ml) Carlzomib (2 mg/ml) Cetuximab (2 mg/ml) Chloroquine (50 mg/ml) Cisplatin (1 mg/ml) Cladribine (1 mg/ml) Cyclophosphamide (20 mg/ml) Cyclosporin A (100 mg/ml) Cytarabine (Cytosine) (100 mg/ml) Cytovene (Ganciclovir) (10 mg/ml) Dacarbazine (DTIC) (10 mg/ml) Dactinomycin (0.5 mg/ml) Daunorubicin HCl (5 mg/ml) Decitabine (5 mg/ml) Docetaxel (10 mg/ml) Doxorubicin HCl (2 mg/ml) Epirubicin HCl (Ellence) (2 mg/ml) Etoposide (Toposar) (20 mg/ml) 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 60 minutes: Carmustine (3.3 mg/ml) No breakthrough up to 0.3 minutes. Thiotepa (10 mg/ml) No breakthrough up to 30.9 minutes. The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 ml) Warning: Do not use with Carmustine or Thiotepa.

Technological Characteristics Comparison Table

	Subject Device K202622	Predicate Device K180646	Comparison
FDA Product Code	LZC, LZA, 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 Lavender Nitrile, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Halyard Lavender, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs	

Intended Use	Halyard Lavender Nitrile, 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 chemotherapy drugs listed on the label.	The Halyard Lavender, 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.	Same
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	Non-Sterile	Non-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 K180646	Remarks
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: 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) Car¬lzomib (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) 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)	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: • Cyclophosphamide (20.0 mg/ml) No breakthrough up to 240 minutes • Doxorubicin HCl (2.0 mg/ml) No breakthrough up to 240 minutes • Etoposide (20.0 mg/ml) No breakthrough up to 240 minutes • 5-Fluorouracil (50.0 mg/ml) No breakthrough up to 240 minutes • Paclitaxel (Taxol) (6.0 mg/ml) No breakthrough up to 240 minutes • Cisplatin (1.0 mg/ml) No breakthrough up to 240 minutes • Dacarbazine (10.0 mg/ml) No breakthrough up to 240 minutes • Ifosfamide (50.0 mg/ml) No breakthrough up to 240 minutes • Mitoxantrone (2.0 mg/ml) No breakthrough up to 240 minutes • Vincristine sulfate (1.0 mg/ml) No breakthrough up to 240 minutes • Carmustine (3.3 mg/ml) No breakthrough up to 0.3 minutes • ThioTEPA (10.0 mg.ml) No breakthrough up to 30.9 minutes Warning: Not for Use With: Carmustine, ThioTEPA	Similar

	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 60 minutes: Carmustine (3.3 mg/ml) No breakthrough up to 0.3 minutes. Thiotepa (10 mg/ml) No breakthrough up to 30.9 minutes.		
Performance Data for Hazardous Drugs (opioids)			
ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100 mcg/2 ml)	Not Tested	Different

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

PERFORMANCE CHARACTERISTICS OF THE SUBJECT DEVICE

Brief description of non-clinical tests:	Test	Standard	Acceptance Criteria	Results
	Dimensions	ASTM D 6319 Length Palm Width Size Finger thickness Palm thickness Cuff thickness	 295 – 325 mm XSmall: 60 – 80 mm Small: 70 - 90 mm Med: 85–105 mm Lrge: 100 - 120 mm X-Lrge: 110-130 mm 0.10-0.19 mm 0.10-0.16 mm 0.10-0.13 mm	Meets requirements
	Physical Properties	ASTM D 6319	AQL 4.0 Before Tensile Strength: ≥14 MPa Ultimate elongation: ≥500% After 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
	Power Free	ASTM D 6124 ASTM D 6319	≤ 2 mg / glove	Meets requirements
	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 for the drugs listed above.	Acceptance criteria: No signs of breakthrough for the subject device after 4 hours for 50 chemotherapy drugs. And for Fentanyl Citrate Injection (100 mcg/2ml)

Conclusion:	The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject device (Halyard Lavender Nitrile, 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 K180646.