June 2, 2022

O&M Halyard, Inc.
Angela Bunn
Director, Global Regulatory Affairs
1 Edison Drive
Alpharetta, Georgia 30005

Re: K220541
Trade/Device Name: PureZero LIMON Nitrile Powder-Free Exam Gloves, PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: April 28, 2022
Received: May 3, 2022

Dear Angela Bunn:

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 Bifeng Qian, Ph D
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

51**O(k)** Number *(if known)*

K220541

Device Name

The PureZero LIMON Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim and PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves

Indications for Use *(Describe)*

The PureZero LIMON Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim and PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim 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 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 HCI (2 mg/ml)
Etoposide (20 mg/ml)	Fluorouracil (50 mg/ml)
Ifosfamide (50 mg/ml)	Methotrexate (25 mg/ml)
Mitomycin C (0.5 mg/ml)	Mitoxantrone HCI (2 mg/ml)
Paclitaxel (6 mg/ml)	Vincrinstine Sulfate (1 mg/ml)
Fentanyl Citrate Injection (100 mcg/2 mL)	Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:

ThioTEPA (10 mg/ml), breakthrough detected at 87.6 minutes

Carmustine (3.3 mg/ml), breakthrough detected at 34.3 minutes

Warning: Not for Use With: Carmustine, ThioTEPA

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

__ Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K220541

Date Summary was Prepared	February 10, 2022
510(k) Submitter	O & M Halyard, Inc. 1 Edison Drive Alpharetta, GA 30005
Primary Contact for this 510(k) Submission	Angela L. Bunn, RAC Tel: 470-347-7147 Email: angela.bunn@owens-minor.com
Marketed Common Name	Nitrile Powder-Free Exam Gloves
Device Submission Trade Name and Description	PureZero LIMON Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim
Device Common Name	Patient Examination 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 1, 21 CFR §880.6250 Fentanyl and Other Opioid Protection Glove
Predicate Device	Halyard Sterling* Nitrile Powder-Free Exam Glove with Chemotherapy Drug and Fentanyl Citrate Claim (K191230)
Subject Device Description	The subject device is a green 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 PureZero LIMON Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim and PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim 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 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) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone HCl (2 mg/ml) Paclitaxel (6 mg/ml) Vincrinstine Sulfate (1 mg/ml) Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes: ThioTEPA (10 mg/ml), breakthrough detected at 87.6 minutes Carmustine (3.3 mg/ml), breakthrough detected at 34.3 minutes Warning: Not for Use With: Carmustine or ThioTEPA

Technological Characteristics Comparison Table			
	Subject Device K220541	Predicate Device Halyard Sterling* Nitrile Powder-Free Exam Glove K191230	Comparison
FDA Product Code	LZC, LZA, QDO	LZC	Added LZA and QDO for the Fentanyl Claim
FDA Classification	Class I	Class I	Same
Regulation Number	880.6250	880.6250	Same
Common Name	Patient Examination Glove	Patient Examination Glove	Same

Device Trade Name	PureZero LIMON Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim	Halyard Sterling* Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs and Fentanyl Citrate claim	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 and gastric acid as listed on the label.	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 and fentanyl citrate listed on the label.	Similar Adding Gastric Acid Claim
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
Glove Length	PureZero LIMON Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim is 9.5 inches in length PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim is 12 inches in length	Halyard Sterling* Nitrile Powder-Free Exam Glove with Chemotherapy Drugs and Fentanyl Citrate is 9.5 inches in length	Similar Adding a longer length glove
Texture	Textured fingertips	Textured fingertips	Same
Sterility	Non-Sterile	Non-Sterile	Same
Shelf Life	3-year	None	Different

Biocompatibility	Based ISO 10993-11 Biological evaluation of Medical devices – Test for Systemic Toxicity, the test article was considered non-toxic. Meets the acceptance criteria.	Based ISO 10993-11 Biological evaluation of Medical devices – Test for Systemic Toxicity, the test article was considered non-toxic. Meets the acceptance criteria.	Same
	Based on ISO 10993-10 Biological evaluation of Medical Devices – Test for Skin Irritation, the test article was considered nonirritating. Meets the acceptance criteria.	Based on ISO 10993-10 Biological evaluation of Medical Devices – Test for Skin Irritation, the test article was considered nonirritating. Meets the acceptance criteria.	
	Based on ISO 10993-10 Biological evaluation of Medical Devices – Test for Skin Sensitization. Under the conditions of the study the device is not a sensitizer. Meets the acceptance criteria.	Based on ISO 10993-10 Biological evaluation of Medical Devices – Test for Skin Sensitization. Under the conditions of the study the device is not a sensitizer. Meets the acceptance criteria.	

Performance Data for Chemotherapy Drugs			
Standard	Results Subject Device(s) PureZero LIMON Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim	Results Predicate Device K191230 Halyard Sterling* Nitrile Powder-Free Exam Glove with Chemotherapy Drugs and Fentanyl Citrate claim	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: 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) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone HCl (2 mg/ml) Paclitaxel (6 mg/ml) Vincrinstine Sulfate (1 mg/ml) Fentanyl Citrate Injection (100 mcg/2 mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes: ThioTEPA (10 mg/ml), breakthrough detected at 87.6 minutes Carmustine (3.3 mg/ml), breakthrough detected at 34.3 minutes.	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes: Arsenic Trioxide (1 mg/ml) Doxorubicin HCL (2 mg/ml) Paclitaxel (6 mg/ml) Azacitidine (Vidaza) (25 mg/ml) Epirubicin (Ellence) (2 mg/ml) Paraplatin (10 mg/ml) Bendamustine (5 mg/ml) Eribulin Mesylate (0.5 mg/ml) Pemetrexed (25 mg/ml) Bortezomib (Velcade) (1 mg/ml) Etoposide (20 mg/ml) Pertuzumab (30 mg/ml) Bleomycin sulfate (15 mg/ml) Fludarabine (25 mg/ml) Raltitrexed (0.5 mg/ml) Busulfan (6 mg/ml) Fluorouracil (50 mg/ml) Retrovir (10 mg/ml) Carboplatin (10 mg/ml) Fulvestrant (50 mg/ml) Rituximab (10 mg/ml) Carfilzomib (2 mg/ml) Gemcitabine (38 mg/ml) Temsirolimus (25 mg/ml) Cetuximab (Erbitux) (2 mg/ml) Idarubicin (1 mg/ml) Trastuzumab (21 mg/ml) Cisplatin (1 mg/ml) Ifosfamide (50 mg/ml) Topotecan HCL (1 mg/ml)	Similar

		Cyclophosphamide (20 mg/ml) Irinotecan (20 mg/ml) Triclosan (2 mg/ml) Cytarabine HCL (100 mg/ml) Mechlorethamine HCL (1 mg/ml) Trisonex (1 mg/ml) Cytovene (10 mg/ml) Melphalan (5 mg/ml) Vincrinstine Sulfate (1 mg/ml) Dacarbazine (10 mg/ml) Methotrexate (25 mg/ml) Vinblastine (1 mg/ml) Daunorubicin HCL (5 mg/ml) Mitomycin-C (0.5 mg/ml) Vinorelbine (10 mg/ml) Decitabine (5 mg/ml) Mitoxantrone (2 mg/ml) Zoledronic Acid (0.8 mg/ml) Docetaxel (10 mg/ml) Oxaliplatin (2 mg/ml) ThioTEPA (10 mg/ml), breakthrough detected at 37.1 minutes Carmustine (3.3 mg/ml), breakthrough detected at 22.9 minutes	

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 physical dimensions of the predicate 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.	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	 235 -250 mm (PureZero LIMON Nitrile) 295- 325 mm (PureZero LIMON-XTRA Nitrile) XSmall: 60 – 80 mm Small: 70 - 90 mm Med: 85–105 mm Large: 100 - 120 mm X-Large: 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	Meets requirements

			Tensile Strength: ≥14 MPa Ultimate elongation: ≥400%	
	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

Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device PureZero LIMON Nitrile Powder- Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim and PureZero LIMON-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim, are as safe, as effective, and performs as well as or better than the legally marketed devices cleared under K191230.