March 10, 2022

Ansell Healthcare Products LLC
Donald Cronk
Associate Director
2301 Robb Drive
Reno, Nevada 89523

Re: K212148
Trade/Device Name: Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: February 28, 2022
Received: March 1, 2022

Dear Donald Cronk:

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,

Clarence W. Murray, III, PhD
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)*

K212148

Device Name
Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drugs have extremely low permeation times: Carmustine: 45.4 minutes and Thiotepa: 23.5 minutes. Warning: Do not use with Carmustine or Thiotepa.

Tested Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine - 3.3 mg/ml	45.4
Cisplatin - 1.0 mg/ml	>240
Cyclophosphamide - 20.0 mg/ml	>240
Dacarbazine - 10.0 mg/ml	>240
Doxorubicin HCl - 2.0 mg/ml	>240
Etoposide - 20.0 mg/ml	>240
Fluorouracil - 50.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Paclitaxel - 6.0 mg/ml	>240
Thiotepa - 10.0 mg/ml	23.5
Vincristine Sulfate - 1.0 mg/ml	>240

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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510K Summary

510(k) Number:
K212148

Submitter:
Ansell Healthcare Products LLC.
2301 Robb Drive
Reno, NV 89523

Contact Person(s):
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Date Prepared:
2/23/2022

Name of the Device:

Trade Names:	Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs
Common Name:	Patient Examination Glove
Classification Name:	Patient Examination Glove
Classification Regulation:	21 CFR 880.6250
Device Class:	I
Product Code:	LZA, LZC
Classification Panel:	Non-powdered patient examination glove

Legally Marketed Predicate Device:

Company:	Ansell Healthcare Products LLC
Trade Names:	Microflex® Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
510(k) Number:	K210401
Device Class:	Class I
Product Code:	LZA, LZC, QDO
Device Name:	Patient Examination Glove (21 CFR 880.6250)

Device Description:
Microflex 73-743 Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs is a non-sterile, single use only, disposable, powder free examination gloves.

Characteristics:

- Ambidextrous with beaded cuff and straight fingers
- Finger-textured
- Blue colored
- Five (5) sizes – extra-small, small, medium, large, and extra-large
- Tested against chemotherapy drugs

High levels of ozone will degrade rubber material of the glove; therefore, the glove should be protected from ozone in particular.

The glove is designed to meet the specifications of ASTM D6977-19, Standard Specification for Polychloroprene Examination Gloves for Medical Application.

Indications for Use Statement:
Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drugs have extremely low permeation times: Carmustine: 45.4 minutes and Thiotepa: 23.5 minutes. Warning: Do not use with Carmustine or Thiotepa.

Tested chemotherapy drugs are as follows:

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGE MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)
Carmustine (3.3 mg/ml)	45.4
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	23.5
Vincristine Sulfate (1.0 mg/ml)	>240

Technological Characteristics:

	Predicate	Subject Device	Comparison
Trade name	Microflex® Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs	Different
Product Owner	Ansell Healthcare	Ansell Healthcare	Same
Product Code	LZA, LZC, QDO	LZA, LZC	Different
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Regulatory Class	I	I	Same
Regulation Name	Patient Examination Glove	Patient Examination Glove	Same
Indications for use	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Same
Material Composition	Synthetic nitrile rubber	Polychloroprene	Different
Coating	Polyacrylic polymer inner coating to aid donning	Polyacrylic polymer inner coating to aid donning	Same
Design	Non-sterile	Non-sterile	Same
	Single use	Single use	Same
	Powder-free	Powder-free	Same
	Ambidextrous	Ambidextrous	Same
	Beaded cuff	Beaded cuff	Same
Color	Blue, Green, and Black	Blue	Different

Performance a. **Dimensions**	Meets ASTM D6319-10 requirements	Meets ASTM D6977-19 requirements	Similar
b. **Physical Properties**	Meets ASTM D6319-10 requirements	Meets ASTM D6977-19 requirements	Similar
c. **Freedom from holes**	Meets ASTM D6319-10 requirements of GI, AQL 2.5	Meets ASTM D6977-19 requirements of GI, AQL 2.5	Similar
d. **Powder Residual**	Meets ASTM D6319-10 requirements; Not more than 2.0mg/glove	Meets ASTM D6977-19 requirements; Not more than 2.0mg/glove	Similar
e. **Sterility**	Non-sterile	Non-sterile	Same
Ozone	Avoid Ozone	Avoid Ozone	Same
Biocompatibility	Passes Primary Skin Irritation Test and Dermal Sensitization Test and Acute Systemic Toxicity Test and *In Vitro* Cytotoxicity Test	Passes Primary Skin Irritation Test and Dermal Sensitization Test and Acute Systemic Toxicity Test and *In Vitro* Cytotoxicity Test	Same
Chemotherapy Claim	Microflex® Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drug has an extremely low permeation time: Carmustine: 47.9 minutes. Warning; Do not use with Carmustine. Tested chemotherapy drugs/concentration & Average Minimum Breakthrough Detection Time (Minutes) are as follows:	Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drugs have extremely low permeation times: Carmustine: 45.4 minutes and Thiotepa: 23.5 minutes. Warning; Do not use with Carmustine or Thiotepa. Tested chemotherapy drugs/concentration & Average Minimum Breakthrough Detection Time (Minutes) are as follows:	Different
	Carmustine (3.3 mg/ml) 47.9	Carmustine (3.3 mg/ml) 45.4	Different
	Cyclophosphamide (20.0 mg/ml) >240	Cyclophosphamide (20.0 mg/ml) >240	Same
	Doxorubicin HCl (2.0 mg/ml) >240	Doxorubicin HCl (2.0 mg/ml) >240	Same
	Etoposide (20.0 mg/ml) >240	Etoposide (20.0 mg/ml) >240	Same

	Fluorouracil (50.0 mg/ml) >240	Fluorouracil (50.0 mg/ml) >240	Same
	Methotrexate (25.0 mg/ml) >240	Methotrexate (25.0 mg/ml) >240	Same
	Paclitaxel (6.0 mg/ml) >240	Paclitaxel (6.0 mg/ml) >240	Same
	Thiotepa (10.0 mg/ml) >240	Thiotepa (10.0 mg/ml) 23.5	Different
	Vincristine Sulfate (1.0 mg/ml) >240	Vincristine Sulfate (1.0 mg/ml) >240	Same
		Cisplatin (3.3 mg/ml) >240	Different
		Dacarbazine (10.0 mg/ml) >240	Different
	Tested hazardous drug & Average Minimum Breakthrough Detection Time (Minutes) are as follows:		Different
	Fentanyl Citrate Injection (100 mcg/2 ml) >240		Different

The subject device meets the applicable requirements for patient examination gloves regarding dimensions and sizes, physical properties, freedom from holes, and powder residues as found in the following standards: ASTM D6977, ASTM D5151 and ASTM D6124.

Non-Clinical Testing:

Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs has the following technological characteristics as compared to ASTM or equivalent standards:

Test Methodology	**Purpose**	**Acceptance Criteria**	**Results**
Physical Characteristics:			
Dimensions:	Standard Specification for Polychloroprene Examination Gloves for Medical Application	ASTM D6977-19	Meets ASTM D6977-19 requirements for length, width and thickness
Length		*Minimum 230mm*	*Minimum 240mm*
Palm width (mm)			
Size – XS		*70 ± 10*	*75 ± 5*
Size – S		*80 ± 10*	*85 ± 5*

Size – M		*95 ± 10*	*95 ± 5*
Size – L		*110± 10*	*105 ± 5*
Size - XL		*120 ± 10*	*115 ± 5*
Thickness (mm) - single-wall			
Finger		*minimum 0.05*	*Finger – min 0.09*
Palm		*minimum 0.05*	*Palm – min 0.06*
Cuff		*-*	*Cuff – min 0.05*
Physical Properties:	Standard Specification for Polychloroprene Examination Gloves for Medical Application	ASTM D6977-19	Meets ASTM D6977-19 requirements for tensile strength and ultimate elongation before and after accelerated aging:
Tensile Strength			
Before Aging		*minimum 14 MPa*	*minimum 16 MPa*
After Aging		*minimum 14 MPa*	*minimum 14 MPa*
Ultimate Elongation			

Before Aging		*minimum 500%*	*minimum 500%*
After Aging		*minimum 400%*	*minimum 400%*
Freedom from holes	Standard Test Method for Detection of Holes in Medical Gloves	ASTM D6977-19 ASTM D5151-06	Meets or exceeds ASTM D6977-19 and ASTM D5151-06 requirements of AQL 2.5
Powder Residual	Standard Test Method for Residual Powder on Medical Gloves	ASTM D6977-19 ASTM D6124-06	Meets applicable requirement for powder free; ≤ 2 mg per glove
Biocompatibility:			
ISO Skin Irritation Study	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	ISO10993-10:2010	Under the conditions of the study, not an irritant
ISO Maximization Sensitization Study	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	ISO 10993-10:2010	Under the conditions of the study, not a sensitizer
ISO Acute Systemic Toxicity	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	ISO 10993-11: 2006	Under the conditions of the study, no evidence of systemic toxicity
ISO *In Vitro* Cytotoxicity	Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study undiluted, 1:2, and 1:4 dilutions were cytotoxic (grade 4). Dilutions of 1:8 (grade 2), 1:16 (grade 1), 1:32 and 1:64 (grade 0) were non-cytotoxic

The subject device passes biological reactivity testing for skin irritation, dermal sensitization, acute systemic toxicity, and *in vitro* cytotoxicity; in accordance with the ISO 10993 series of standards.

A clinical study was not required for the subject or predicate device.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device.