August 10, 2021

American Performance Polymers, LLC
% Natalie Vollrath
Sr. Regulatory Consultant
MEDIcept, Inc.
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K210730
Trade/Device Name: Nitrile Patient Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: Jun 23, 2021
Received: Jun 24, 2021

Dear Natalie Vollrath:

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 Clarence W. Murray III, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210730

Device Name
Nitrile Patient Examination Glove

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 or finger to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
Carmustine (BCNU), 3 .3 mg/ml	33.3
Cisplatin, 1.0 mg/ml	> 240
Cyclophosphamide (Cytoxan). 20.0 mg/ml	> 240
Cytarabine Hydrochloride, 100 mg/ml	> 240
Dacarbazine (DTIC), 10.0 mg/ml	> 240
Daunorubicin, 5 mg/ml	> 240
Doxorubicin Hydrochloride, 2.0 mg/ml	> 240
Etoposide (Toposar), 20.0 mg/ml	> 240
Fluorouracil, 50.0 mg/ml	> 240
lfosfamide, 50.0 mg/ml	> 240
Methotrexate, 25.0 mg/ml	> 240
Mitomycin C, 0.5 mg/ml	> 240
Mitoxantrone, 2mg/ml	> 240
Paclitaxel (Taxol), 6.0 mg/ml	> 240
Thiotepa, 10.0 mg/ml	66.2
Vincristine Sulfate, 1.0 mg/ml	> 240
Fentanyl Citrate, 100mcg/2mL	> 240

Please note the following drugs have low permeation times:
Carmustine (BCNU) (3.3mg/ml) 33.3 minutes
Thiotepa (10.0mg/ml) 66.2 minutes

Warning: Do not use these gloves with Carmustine or 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
(per 21 CFR 807.92)

1.0 Submitter/510(k) Holder

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Contact Person: Natalie Vollrath
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nvollrath@medicept.com

Date Prepared: August 5, 2021

2.0 Device Name

Proprietary Name:	Pilgrim Nitrile Medical Examination Glove
Common Name:	Powder-Free Nitrile Patient Examination Glove
Classification Name:	Polymer Patient Examination Glove
Regulation Number:	21 CFR 880.6250
Product Code:	LZA, LZC, OPJ, QDO
Classification Panel:	General Hospital
Device Classification:	Class I, reserved

3.0 Predicate Device

K192954 – Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (21CFR 880.6250, Product Code: LZA, LZC, QDO)

4.0 Device Description

The Nitrile Medical Examination Glove is a non-sterile, single-use, disposable glove intended for medical purposes to be worn on the hands of examiners to prevent contamination between an examiner and the patient. The gloves are made of nitrile butadiene rubber and are white-colored and powder-free. The gloves are offered in one version in a range of sizes: x-small, small, medium, large, and x-large.

5.0 Intended Use/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 or finger to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)
Carmustine (BCNU) 3 .3 mg/ml	33.3
Cisplatin 1.0 mg/ml	> 240
Cyclophosphamide (Cytoxan) 20.0 mg/ml	> 240
Cytarabine 100 mg/ml	> 240
Dacarbazine 10.0 mg/ml	> 240
Daunorubicin HCI 5.0 mg/ml	> 240
Doxorubicin HCI 2.0 mg/ml	> 240
Etoposide 20.0 mg/ml	> 240
Fluorouracil 50.0 mg/ml	> 240
lfosfamide 50.0 mg/ml	> 240
Methotrexate 25.0 mg/ml	> 240
Mitoxantrone 2mg/ml	> 240
Paclitaxel (Taxol) 6.0 mg/ml	> 240
Thiotepa 10.0 mg/ml	66.2
Vincristine Sulfate 1.0 mg/ml	> 240

Tested Fentanyl Citrate is as follows:

Fentanyl Citrate 100mcg/2mL	> 240

Please note the following drugs have low permeation times:
Carmustine (BCNU) (3.3mg/ml) 33.3 minutes
Thiotepa (10.0mg/ml) 66.2 minutes

Warning: Do not use these gloves with Carmustine or Thiotepa

6.0 Technological Characteristics and Substantial Equivalence

The Nitrile Patient Examination Gloves are summarized within the the following table comparing technological characteristics to the ASTM of the subject gloves to the predicate device.

	Proposed Device **K210730**	**Predicate Device** **K192954**	**Comparison**
Device Classification Name	Patient Examination Glove	Patient Examination Glove	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Product Code	LZA, LZC, OPJ, QDO	LZA, LZC, QDO	Similar
Intended Use	The Nitrile Patient Examination Glove, non-sterile and powder-free is a disposable device intended for medical purposed that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves have been tested for permeation and breakthrough resistance against various types of chemotherapy drugs and Fentanyl Citrate	The Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs and Fentanyl Citrate	Similar
Prescription v. OTC	OTC	OTC	Same
Dimension ASTM D6319 - 10	Length-XS >229mm, S, M, L, XL >239mm Thickness palm and finger- >0.075mm	Length-Min 240mm Thickness palm and finger- Min 0.05mm	Similar
	Palm width: XS 70 ± 10mm S 80 ± 10mm M 95 ± 10mm L 110 ± 10mm XL 120 ± 10mm	-------	Different

	Proposed Device K210730	Predicate Device K192954	Comparison
Physical Properties ASTM D6319 - 10	Meets	Meets	Same
Thickness – Finger, Palm ASTM D6319 - 10	Meets	Meets	Same
Powder Content ASTM – D6124 – 06 (≤2 mg/glove)	Meets	Meets	Same
Chemotherapy Drug Permeation Test ASTM D6978-05			
Chemotherapy Drug with Concentration:	**Minimum Breakthrough Detection Time (Min.)**		
Cisplatin 1.0 mg/ml	>240	>240	Same
Cyclophosphamide (Cytoxan) 20.0 mg/ml	>240	>240	Same
Cytarabine 100 mg/ml	>240	---	Different
Dacarbazine 10.0 mg/ml	>240	>240	Same
Daunorubicin HCl 5.0 mg/ml	>240	---	Different
Doxorubicin HCl 2.0 mg/ml	>240	>240	Same
Etoposide 20.0 mg/ml	>240	>240	Same
Fluorouracil 50.0 mg/ml	>240	>240	Same
Ifosfamide 50.0 mg/ml	>240	>240	Same
Methotrexate 25.0 mg/ml	>240	---	Different
Mitoxantrone 2mg/ml	>240	>240	Same
Paclitaxel (Taxol) 6.0 mg/ml	>240	>240	Same
Vincristine Sulfate 1.0 mg/ml	>240	>240	Same

	Proposed Device K210730	Predicate Device K192954	Comparison
Carmustine (BCNU) 3 .3 mg/ml	33.3	18.2	Similar
Thiotepa 10.0 mg/ml	66.2	57.3	Similar
Warning Statement	Please note that the following drugs have low permeation times Carmustine (BCNU): 33.3 minutes and Thiotepa: 66.2 minutes Warning: Do not use with Carmustine or Thiotepa	* WARNING Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 18.2 minutes and Thiotepa: 57.3 minutes	Similar
Fentanyl Citrate Permeation Test ASTM D6978-05			
With Concentration:	**Minimum Breakthrough Detection Time (Min.)**		
Fentanyl Citrate 100mcg/2mL	>240	>240	Same
Biocompatibility: Irritation ISO 10993-10	Passes Under the conditions of the study, the subject device is non-irritating	Passes Under the conditions of the study, the subject device is non-irritating	Same
Biocompatibility: Skin Sensitization ISO 10993-10	Passes Under the conditions of the study, the subject device is non-sensitizing	Passes Under the conditions of the study, the subject device is non-sensitizing	Same

	Proposed Device **K210730**	**Predicate Device** **K192954**	**Comparison**
Biocompatibility: Cytotoxicity ISO 10993-5	Exhibits severe cytotoxicity reactivity at 100%	Exhibits severe cytotoxicity reactivity at 100%, and 66% extract concentrations and no cytotoxicity reactivity at 44%, 30%, 20% and 15% extract concentrations under the condition of this test	Similar
Biocompatibility: Acute Systemic Toxicity ISO 10993-11	Passes Additional acute systemic toxicity testing results showed no systemic toxicity concern	Passes Under the conditions of the study, the subject showed no adverse biological reaction	Similar
Pinhole Test	Passes	Passes	Same
Material	Nitrile	Nitrile	Same
Color	White	Blue	Different
Size	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Same
Sterile v. Non-Sterile	Non-Sterile	Non-Sterile	Same
Single-Use v. Reusable	Single-Use	Single-Use	Same

The Chemotherapy claim is similar to the predicate, which has a glove thickness that complies with the ASTM Standards. Compared with the predicate, the subject device was tested with additional chemotherapy drugs.

7.0 Performance Testing

Non-clinical testing was performed to demonstrate that the proposed device meets requirements.

Test Method	Purpose	Acceptance Criteria	Results
ISO 10993-10	Irritation	Not a skin irritant	The subject device is non-irritating
ISO 10993-10	Skin Sensitivity	Not a skin sensitizer	The subject device is non-sensitizing
ISO 10993-5	Cytotoxicity	No cytotoxic reactivity	Failed
ISO 10993-11	Acute Systemic Toxicity	No systemic reactivity	Pass
ASTM D6978	Permeation of Chemotherapy Drugs	≥240 minutes breakthrough time	Pass
ASTM D6978	Permeation of Fentanyl	≥240 minutes breakthrough time	Pass
ASTM D6124	Powder Residue	2 mg/glove maximum	Pass
ASTM D5151	Pinhole Test	Free from holes, AQL 1.5	Pass
ASTM D6319	Physical Properties	Before aging Tensile strength: Min. 14 MPa Elongation: Min. 500% After aging Tensile strength: Min. 14 MPa Elongation: Min. 400%	Pass

8.0 Conclusion

Results from non-clinical performance testing to applicable standards demonstrate that the proposed Pilgrim Gloves are as safe and effective as the legally marketed predicate gloves.