January 19, 2022

Uweport LLC.
% Elaine Duncan
President
Paladin Medical, Inc
P.O. Box 560
Stillwater, Minnesota 55082

Re: K213227
Trade/Device Name: Uweport Powder-Free Nitrile Examination Gloves 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, OPJ
Dated: December 17, 2021
Received: December 20, 2021

Dear Elaine Duncan:

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)*
K213227

Device Name
Uweport Powder-Free NITRILE EXAMINATION GLOVES Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
Uweport Powder-Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs is a non-sterile, single-use, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These Gloves have been tested for use with chemotherapy drugs per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Drug Tested	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	22.8
Cisplatin	1 mg/ml (1.000 ppm)	>240
Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	>240
Dacarbazine	10 mg/ml (10,000 ppm)	>240
Doxorubicin	2 mg/ml (2,000 ppm)	>240
Etoposide	20 mg/ml (20,000 ppm)	>240
Fluorouracil	50.0 mg/ml (50.000 ppm)	>240
Paclitaxel,	6 mg/ml (6,000 ppm)	>240
ThioTepa,	10.0 mg/ml (10,000 ppm)	46.8

Warning: Not recommended for use with Carmustine and Thiotepa. The maximum testing time is 240 minutes. Please note that the following drugs have low permeation times:

Camustine (BCNL) 3.3 mg/ml (3,000 ppm) 22.8 minutes
Thiotepa 10.0 mg/ml (10,000 ppm) 46.8 minutes

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.

510(K) SUMMARY K213227

Submitter: : **Uweport, LLC .**
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Charlotte, NC 28211
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Email: mwang@uweport.com

510(k) CONTACT: **Elaine Duncan, M.S.M.E., RAC**
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: **715-549-6035**

DATE PREPARED: **January 14, 2022**

PRODUCT NAME: **Uweport Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs**

COMMON NAME: **Examination Glove**

CLASSIFICATION NAME **Medical Gloves with Chemotherapy Labeling Claims Test for use with Chemotherapy Drugs**

CLASSIFICATION **Class I**

PRO CODE: **LZA, OPJ, LZC**

REGULATION **21 CFR 880.6250**

PREDICATE NAME: **K210944 Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs)**

DESCRIPTION of the DEVICE:

Uweport Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a non-sterile, single-use, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These Gloves have been tested for use with chemotherapy drugs per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. These powder-free gloves are made of synthetic biocompatible copolymer of acrylonitrile and butadiene with a blue color additive. The gloves are available in small, medium, large, and extra-large.

INDICATIONS FOR USE:

Uweport Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a non-sterile, single-use, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These Gloves have been tested for use with chemotherapy drugs per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

List of Drugs tested concentration and breakthrough detection time in minutes.

Drug Tested	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	22.8
Cisplatin	1 mg/ml (1,000 ppm)	>240
Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	>240
Dacarbazine	10 mg/ml (10,000 ppm)	>240
Doxorubicin	2 mg/ml (2,000 ppm)	>240
Etoposide	20 mg/ml (20,000 ppm)	>240
Fluorouracil	50.0 mg/ml (50,000 ppm)	>240
Paclitaxel,	6 mg/ml (6,000 ppm)	>240
ThioTepa,	10.0 mg/ml (10,000 ppm)	46.8

Warning: Not recommended for use with Carmustine and Thiotepa. The maximum testing time is 240 minutes.		
Please note that the following drugs have low permeation times:		
Camustine (BCNL)	3.3 mg/ml (3,000 ppm)	22.8 minutes
Thio tepa	10.0 mg/ml (10,000 ppm)	46.8 minutes

Comparative Analysis to Predicate:

Characteristic	Predicate Device	UWEPORT	ComparisonAnalysis
Device Name	Harbour Health Powder Free Nitrile Examination Glove, Blue(Tested for Use with Chemotherapy Drugs)	Uweport Nitrile Exam Glove (tested for use with Chemotherapy Drugs)	
510(k) Reference	K210944	K213227	
Product Code	LZA, LZC, OPJ	LZA, LZC, OPJ	Same
Indication for Use (partial)	The Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The proposed device was tested for use with chemotherapy drugs per ASTM D6978-05(2019), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	**Uweport Powder-Free Nitrile Exam Gloves Tested for Use with Chemotherapy Drugs** is a non-sterile, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These Gloves have been tested for use with chemotherapy drugs per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Material	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
Design Features	Ambidextrous Textured fingertipsBeaded cuff Straight fingers	Ambidextrous Textured fingertips Beaded cuff Straight fingers	Similar
Sizes	Small, Medium, Large, ExtraLarge	Small, Medium,Large, Extra Large	Same
Dimension Thickness	Complies with ASTM D6319-19 Palm: 0.05mm min. Finger: 0.05mm min.	Complies with ASTM D6319-19 Palm: 0.07S; 0.08M; .08L, 0.08mmXL all ±0.03mm Finger: 0.09 ± 0.03	Similar
Dimensions-Width	Complies with ASTM D6319-19 Small: 80± 10mm	Complies with ASTM D6319-19 Small: 85± 5mm	Similar

Characteristic	Predicate Device	UWEPORT	ComparisonAnalysis
	Medium:95± 10mm Large:110± 10mm Extra Large:120 ±10mm	Medium:96± 5mm Large:108± 5mm Extra large:115±5mm	
Dimensions Length	Complies with **ASTM D6319-19** Small: 220mm min. Medium/Large/Extra Large: 230mm- min	Complies with **ASTM D6319-19** Small: ≥220mm. Medium/Large/Extra Large: ≥240mm	
Rx vs OTC	OTC	OTC	Same
Sterile vs Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs Non-Disposable	Disposable	Disposable	Same
Biocompatibility	Complies with **ANSI/AAMI/ISO *10993-5* (2009)** * Under the conditions of the study, the device is potentially cytotoxic. Complies with **ANSI/AAMI/ISO 10993-10** (2010) * Under the conditions of the study, the device is a nonirritant and a non-sensitizer. Complies with **ANSI/AAMI/ISO 10993-11 (2017)** * Under the conditions of the study, the device does not elicit a systemic toxicity response in the model animal.	**Cytotoxicity** ISO 10993-5: At 100% extraction the cell viability was 17.1%. **Sensitization** ISO 10993-10 The test article passed both extract assays with a 0 score. **Irritation** ISO 10093-10 The test article from both extracts was categorized as negligible under the test conditions. **Acute Systemic Toxicity;** ISO 10993-11:2017; Under the conditions of the study the test article extract met the requirements of the study; Body weight data and animal appearance was normal throughout the study.	Similar
Single Use vs Reusable	Single Use	Single Use	Same
Physical Properties Tensile Strength	Complies with ASTM D6319-19 Before Aging: >14 MPa min. After Aging: >14 MPa, min.	Complies with ASTM D6319-19 at nominal conditions ≥14 Mpa	Similar
Physical Properties Elongation-	Complies with ASTM D6319-19 Before Aging: 500% min. After Aging:400% min.	Complies with ASTM D6319-19 at nominal conditions; ≥500	similar
Freedom from Holes	Complies with ASTM D5151-19 and ASTM D5151-19 G-1, AQL 2.5	Complies with ASTM D5151-19; AQL = 2.5, 125 samples from batch of 35000, inspection level 1, criterion ≤7 Zero nonconforming	Similar
Residual Powder	Complies with ASTM D6319-19 < 2 mg per glove	ASTM D6124 Standard Test Method for Residual Powder On Medical Gloves; residual powder 0.15; 0.18 and 0.19 mg/glove;	Similar

Characteristic	Predicate Device	UWEPORT	ComparisonAnalysis
Chemotherapy Permeation	ASTM D6978-05(2019) Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	ASTM D6978-05(2019) Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Uweport gloves met requirements for testing drugs listed in standard; results of predicate not known

SUMMARY of Non-Clinical TESTING:

TESTING FOR	STANDARD/METHOD	ACCEPTANCE CRITERIA	RESULTS
Specifications	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	Per Standard- AQL = 2.5 and various	See comparative chart above for individual results
Holes in glove	ASTM D5151-2006 Standard Test Method for Detection of Holes in Medical Gloves	AQL = 2.5, 125 samples from batch of 35000, inspection level 1, criterion ≤7 Zero nonconforming	Zero nonconforming
Resistance to chemotherapy drugs	ASTM D6978-05(2019) Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Per standard	See indication for use for details
Residual powder	ASTM D6124 Standard Test Method for Residual Powder On Medical Gloves	residual powder 0.15; 0.18 and 0.19 mg/glove;	test results acceptable
Biocompatibility	FDA Guidance document "Use of ISO 10993-1 issued June 16, 2016" and Part 5, Part 10:	According to biological reactivity to L929 cells; According to patch test reaction; According to irritation index	Passed all testing; see comparative chart for details

CLINICAL TESTING not required

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