February 9, 2023

Nephron Pharmaceuticals Corporation
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K223559
Trade/Device Name: Nephron Nitrile 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: February 1, 2023
Received: February 1, 2023

Dear Prithul Bom:

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,

Allan Guan -S

For Bifeng Qian, M.D., 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)*
K223559

Device Name
Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs)

Indications for Use *(Describe)*
Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs) is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) 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:

Bleomycin Sulfate (15.0 mg/ml)	Doxorubicin HCl (2.0 mg/ml)	Mechlorethamine HCl (1.0 mg/ml)
Busulfan (6.0 mg/ml)	Epirubicin HCl (2.0 mg/ml)	Melphalan (5.0 mg/ml)
Carboplatin (10.0 mg/ml)	Etoposide (20.0 mg/ml)	Methotrexate (25.0 mg/ml)
Cisplatin (1.0 mg/ml)	Fludarabine (25.0 mg/ml)	Mitomycin C (0.5 mg/ml)
Cyclophosphamide (20.0 mg/ml)	Fluorouracil (50.0 mg/ml)	Mitoxantrone HCl (2.0 mg/ml)
Cytarabine (100.0 mg/ml)	Gemcitabine (38.0 mg/ml)	Paclitaxel (6.0 mg/ml)
Dacarbazine (10.0 mg/ml)	Idarubicin HCl (1.0 mg/ml)	Rituximab (10.0 mg/ml)
Daunorubicin HCl (5.0 mg/ml)	Ifosfamide (50.0 mg/ml)	Trisenox (1.0 mg/ml)
Docetaxel (10.0 mg/ml)	Irinotecan (20.0 mg/ml)	Vincristine Sulfate (1.0 mg/ml)

The following chemotherapy drugs have low permeation times:
Carmustine (3.3 mg/ml) : 33.8 minutes Thiotepa (10.0 mg/ml) : 128.1 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) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY K223559

AS REQUIRED BY: 21CFR§807.92

A. APPLICANT INFORMATION

510(K) Owner's Name	Nephron Pharmaceuticals Corporation
Address	4500 12th Street Extension, West Columbia, SC 29172.
Phone	1-803-569-3110
Fax	1-803-926-9853
E-mail	lkennedy@nephronpharm.com
Contact Person	Lou Kennedy
Designation	Chief Executive Officer
Contact Number	1-803-569-3110
Contact Email	lkennedy@nephronpharm.com
Date Submitted	21 October 2022

B. DEVICE IDENTIFICATION

Name of the device	Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs)
Product proprietary or trade name	Nephron Nitrile
Common or usual name	Nitrile Examination Gloves (Tested for use with Chemotherapy drugs)
Classification name	Non-Powdered Patient Examination Glove Specialty
Device Classification	Class-1, Reserved
Product Code	LZA, LZC, OPJ
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital and Personal Use Devices

C. PREDICATE DEVICE

Predicate Device	Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested for Use with Chemotherapy Drugs
510(k) Number	K213440
Regulatory Class	Class-1
Product code	LZA, LZC

Reference Device	SHOWA® Blue Nitrile Powder Free Medical Examination Glove
510(k) Number	K211003
Regulatory Class	Class-1
Product code	LZA, LZC

D. DESCRIPTION OF THE DEVICE:

Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs) is a Class I, patient examination gloves bearing the product codes LZA, LZC, OPJ (21CFR880.6250). They meet all the current specifications listed under the ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application and also complies with requirements for Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs as per ASTM D6978-05 (2019). They are made from Nitrile (NBR). These gloves are blue in color and are powder free. The product is non-sterile, fingertip textured, ambidextrous with beaded cuff and single use only.

Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs) with sizes Medium, Large, X-Large and XX-Large are included in the submission.

E. INDICATION FOR USE OF THE DEVICE:

Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs) is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) 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:		
Bleomycin Sulfate (15.0 mg/ml)	**Doxorubicin HCl** (2.0 mg/ml)	**Mechlorethamine HCl** (1.0 mg/ml)
Busulfan (6.0 mg/ml)	**Epirubicin HCl** (2.0 mg/ml)	**Melphalan** (5.0 mg/ml)
Carboplatin (10.0 mg/ml)	**Etoposide** (20.0 mg/ml)	**Methotrexate** (25.0 mg/ml)
Cisplatin (1.0 mg/ml)	**Fludarabine** (25.0 mg/ml)	**Mitomycin C** (0.5 mg/ml)
Cyclophosphamide (20.0 mg/ml)	**Fluorouracil** (50.0 mg/ml)	**Mitoxantrone HCl** (2.0 mg/ml)
Cytarabine (100.0 mg/ml)	**Gemcitabine** (38.0 mg/ml)	**Paclitaxel** (6.0 mg/ml)
Dacarbazine (10.0 mg/ml)	**Idarubicin HCl** (1.0 mg/ml)	**Rituximab** (10.0 mg/ml)
Daunorubicin HCl (5.0 mg/ml)	**Ifosfamide** (50.0 mg/ml)	**Trisenox** (1.0 mg/ml)
Docetaxel (10.0 mg/ml)	**Irinotecan** (20.0 mg/ml)	**Vincristine Sulfate** (1.0 mg/ml)
The following chemotherapy drugs have low permeation times: **Carmustine** (3.3 mg/ml) : 33.8 minutes **Thiotepa** (10.0 mg/ml) : 128.1 minutes		
Warning: Not for Use with: Carmustine, Thiotepa		

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	K213440	K211003	K223559	
Name of device	---	Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested for Use with Chemotherapy Drugs	SHOWA® Blue Nitrile Powder Free Medical Examination Glove	Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs)	Similar to predicate device
Product Code	---	LZA, LZC	LZA, LZC	LZA, LZC, OPJ	Similar
Indication for use	---	Powder Free Nitrile Examination Gloves (Blue, Purple-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.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by chemotherapy drugs.	Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs) is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Similar
Regulation Number	---	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same
Material	---	Nitrile	Nitrile	Nitrile	Same
Color	---	Blue, Purple-Blue	Blue	Blue	Same
Size	---	XS, S, M, L, XL, XXL	XS, S, M, L, XL	M, L, XL, XXL	Similar

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	K213440	K211003	K223559	
Single Use	---	Single-use	Single-use	Single-use	Same
Sterile/non sterile	---	Non Sterile	Non Sterile	Non Sterile	Same
Rx Only or OTC	---	OTC	OTC	OTC	Same
Dimensions - Length	ASTM D6319-19	Minimum 230mm	Overall Length (mm) = 220 mm (sizes XS – S) and 230 mm (sizes M – XL)	Minimum 230 mm **Size** / **Average value** M: 235 L: 237 XL: 250 XXL: 238	Similar
Dimensions - Width	ASTM D6319-19	XS: 70±10 S: 80±10 M: 95±10 L: 110±10 XL: 120±10 XXL: 130±10	Width (± 10 mm) Size XS = 70 mm Size S = 80 mm Size M = 95 mm Size L = 110 mm Size XL = 120 mm	M: 95±10 mm L: 110±10 mm XL: 120±10 mm XXL: 130±10 mm **Size** / **Average value** M: 95 L: 113 XL: 121 XXL: 129	Same
Physical Properties-Tensile Strength	ASTM D6319-2019	Before aging 14MPa, min	Before aging (MPa) = 14 min	Before aging 14MPa, min Average value = 34.0 MPa (Medium)	Same
		After aging 14MPa, min	After aging (MPa) = 14 min	After aging 14MPa, min Average value = 37.3 MPa (Medium)	Same
Physical Properties-Ultimate Elongation	ASTM D6319-2019	Before aging 500%, min	Before aging (%) = 500 min	Before aging 500%, min Average value = 542% (Medium)	Same
		After aging 400%, min	After aging (%) = 400 min	After aging 400%, min Average value = 503% (Medium)	Same
Thickness	ASTM D6319-19	Palm: Minimum 0.05 mm Finger: Minimum 0.05 mm	Palm (mm) = 0.05 min Finger Tip (mm) = 0.05 min	Palm: Minimum 0.05 mm Finger: Minimum 0.05 mm **Size** / **Palm (Avg value)** / **Finger (Avg value)** M: 0.077 / 0.111 L: 0.106 / 0.109 XL: 0.089 / 0.115 XXL: 0.113 / 0.107	Same

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	K213440	K211003	---	
Powder Free Residue	ASTM D6319-19	≤ 2 mg per glove	≤ 2.0 mg/pc	≤ 2 mg per glove Average value = 0.3516 mg/glove (Medium)	Same
Freedom from holes	ASTM D5151-2019	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	AQL 2.5 Inspection Level G-1	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	Same
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time	ASTM D6978-05 (2019)	Bleomycin Sulfate 15 mg/ml (15,000 ppm) >240 Minutes	Blenoxane (15.0 mg/ml) >240 Minutes	Bleomycin Sulfate 15 mg/ml (15,000 ppm) >240 Minutes	Same
		Busulfan 6 mg/ml (6,000 ppm) >240 Minutes	Busulfan (6.0 mg/ml) >240 Minutes	Busulfan 6 mg/ml (6,000 ppm) >240 Minutes	Same
		Carboplatin 10 mg/ml (10,000 ppm) >240 Minutes	Carboplatin (10.0 mg/ml) >240 Minutes	Carboplatin 10 mg/ml (10,000 ppm) >240 Minutes	Same
		Carmustine 3.3 mg/ml (3,300 ppm) 25.5 Minutes	Carmustine (3.3 mg/ml) 73.7 Minutes	Carmustine 3.3 mg/ml (3,300 ppm) 33.8 Minutes	Similar
		Chloroquine 50mg/ml (50,000ppm) >240 Minutes	---	Not tested	Optional*
		Cisplatin 1 mg/ml (1,000 ppm) >240 Minutes	Cisplatin (1.0 mg/ml) >240 Minutes	Cisplatin 1 mg/ml (1,000 ppm) >240 Minutes	Same
		Cyclophosphamide 20 mg/ml (20,000 ppm) >240 Minutes	Cyclophosphamide (20.0 mg/ml) >240 Minutes	Cyclophosphamide 20 mg/ml (20,000 ppm) >240 Minutes	Same
		Cyclosporin 100 mg/ml (100,000 ppm) >240 Minutes	---	Not tested	Optional*
		Cytarabine HCL 100 mg/ml (100,000 ppm) >240 Minutes	---	Not tested	Optional*
		---	Cytarabine (100.0 mg/ml) >240 Minutes	Cytarabine 100 mg/ml (100,000 ppm) >240 Minutes	Same as reference device
		Dacarbazine 10 mg/ml (10,000 ppm) >240 Minutes	Dacarbazine (10.0 mg/ml) >240 Minutes	Dacarbazine 10 mg/ml (10,000 ppm) >240 Minutes	Same

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	K213440	K211003	---	
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time	ASTM D6978-05 (2019)	Daunorubicin HCL 5 mg/ml (5,000 ppm) >240 Minutes	Daunorubicin HCl (5.0 mg/ml) >240 Minutes	Daunorubicin HCl 5 mg/ml (5,000 ppm) >240 Minutes	Same
		Docetaxel HCL 10 mg/ml (10,000 ppm) >240 Minutes	---	Not tested	Optional*
		---	Docetaxel (10.0 mg/ml) >240 Minutes	Docetaxel 10 mg/ml (10,000 ppm) >240 Minutes	Same as reference device
		Doxorubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes	Doxorubicin HCl (2.0 mg/ml) >240 Minutes	Doxorubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes	Same
		Epirubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes	Epirubicin HCl (2.0 mg/ml) >240 Minutes	Epirubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes	Same
		Etoposide 20 mg/ml (20,000 ppm) >240 Minutes	Etoposide (20.0 mg/ml) >240 Minutes	Etoposide 20 mg/ml (20,000 ppm) >240 Minutes	Same
		Fludarabine 25 mg/ml (25,000 ppm) >240 Minutes	Fludarabine (25.0 mg/ml) >240 Minutes	Fludarabine 25 mg/ml (25,000 ppm) >240 Minutes	Same
		Fluorouracil 50 mg/ml (50,000 ppm) >240 Minutes	Fluorouracil (50.0 mg/ml) >240 Minutes	Fluorouracil 50 mg/ml (50,000 ppm) >240 Minutes	Same
		Gemcitabine 38 mg/ml (38,000 ppm) >240 Minutes	Gemcitabine (38.0 mg/ml) >240 Minutes	Gemcitabine 38 mg/ml (38,000 ppm) >240 Minutes	Same
		Idarubicin HCl 1 mg/ml (1,000 ppm) >240 Minutes	Idarubicin HCl (1.0 mg/ml) >240 Minutes	Idarubicin HCl 1 mg/ml (1,000 ppm) >240 Minutes	Same
		Ifosfamide 50 mg/ml (50,000 ppm) >240 Minutes	Ifosfamide (50.0 mg/ml) >240 Minutes	Ifosfamide 50 mg/ml (50,000 ppm) >240 Minutes	Same
		Irinotecan 20 mg/ml (20,000 ppm) >240 Minutes	Irinotecan (20.0 mg/ml) >240 Minutes	Irinotecan 20 mg/ml (20,000 ppm) >240 Minutes	Same
		Mechlorethamine HCl 1 mg/ml (1,000 ppm) >240 Minutes	Mechlorethamine HCl (1.0 mg/ml) >240 Minutes	Mechlorethamine HCl 1 mg/ml (1,000 ppm) >240 Minutes	Same
		Melphalan 5 mg/ml (5,000 ppm) >240 Minutes	Melphalan (5.0 mg/ml) >240 Minutes	Melphalan 5 mg/ml (5,000 ppm) >240 Minutes	Same

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	K213440	K211003	---	
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time	ASTM D6978-05 (2019)	Methotrexate 25 mg/ml (25,000 ppm) >240 Minutes	Methotrexate (25.0 mg/ml) >240 Minutes	Methotrexate 25 mg/ml (25,000 ppm) >240 Minutes	Same
		Mitomycin 0.5 mg/ml (500 ppm) >240 Minutes	Mitomycin C (0.5 mg/ml) >240 Minutes	Mitomycin C 0.5 mg/ml (500 ppm) >240 Minutes	Same
		Mitoxantrone HCL 2 mg/ml (2,000 ppm) >240 Minutes	---	Mitoxantrone HCl 2 mg/ml (2,000 ppm) >240 Minutes	Same as predicate device
		---	Mitoxantrone (2.0 mg/ml) >240 Minutes	Not tested	Optional*
		Oxaliplatin 5mg/ml (5,000ppm) >240 Minutes	---	Not tested	Optional*
		Paclitaxel 6 mg/ml (6,000 ppm) >240 Minutes	Paclitaxel (6.0 mg/ml) >240 Minutes	Paclitaxel 6 mg/ml (6,000 ppm) >240 Minutes	Same
		Paraplatin/Carboplatin, 10mg/ml (10,000ppm) >240 Minutes	---	Not tested	Optional*
		Retrovir 10mg/ml (10,000ppm) >240 Minutes	---	Not tested	Optional*
		Rituximab 10mg/ml (10,000 ppm) >240 Minutes	Rituximab (10.0 mg/ml) >240 Minutes	Rituximab 10 mg/ml (10,000 ppm) >240 Minutes	Same
		Thiotepa 10mg/ml (10,000 ppm) 66.8 Minutes	ThioTepa (10.0 mg/ml) 25.4 Minutes	Thiotepa 10 mg/ml (10,000 ppm) 128.1 Minutes	Similar
		Topotecan 1mg/ml (1,000ppm) >240 Minutes	---	Not tested	Optional*
		Trisenox 1 mg/ml (1,000 ppm) >240 Minutes	Trisenox (1.0 mg/ml) >240 Minutes	Trisenox 1 mg/ml (1,000 ppm) >240 Minutes	Same
		Velcade (Bortezomib) 1mg/ml (1,000ppm) >240 Minutes	---	Not tested	Optional*
		Vincristine Sulfate 1 mg/ml (1,000 ppm) >240 Minutes	Vincristine Sulfate (1.0 mg/ml) >240 Minutes	Vincristine Sulfate 1 mg/ml (1,000 ppm) >240 Minutes	Same

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	K213440	K211003	K223559	
Biocompatibility	Primary Skin Irritation- ISO 10993-23: First Edition 2021-01	Under the conditions of the study, not an irritant	Under the conditions of the study, not a primary skin irritant.	Under the conditions of the study, the test article met the requirements of the test	Same
	Dermal Sensitization- ISO 10993-10: Fourth Edition 2021-11	Under the conditions of the study, not a sensitizer	Under conditions of the study, not a contact sensitizer	Under the conditions of the study, the test article was not considered a sensitizer	Same
	In vitro cytotoxicity- ISO 10993-5: Third Edition 2009-06-01	Under the conditions of this study, the test article extract showed potential toxicity	-----	Under the conditions of the study, the undiluted test article extract and 50% test article extract dilution did not meet the requirements of the test and the 25%, 12.5%, 6.25%, and 3.13% test article extract dilutions met the requirements of the test	Similar to predicate device
	Acute Systemic Toxicity- ISO 10993-11: Third Edition 2017-09	Under the conditions of this study, there was no evidence of systemic toxicity.	Under conditions of the ISO Acute Systemic Injection test, not toxic	Under the conditions of the study, there was no mortality or evidence of systemic toxicity	Same

* Predicate device / reference device perform additional Chemotherapy drug test.

Reference device has been included in the 510k to prove the safety of subject device with respect to the use of chemotherapy drug Cytarabine and Docetaxel which was not tested in case of predicate device.

There are no significant differences between the products and are identical in terms of intended use, materials, design and manufacturing methods. The devices meet the ASTM standard D6319-19 and D6978-05 (2019).

G. NON-CLINICAL TESTING SUMMARY PERFORMANCE DATA

BENCH TEST DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the length of the gloves	Medium : 230 mm min Large : 230 mm min X-Large : 230 mm min XX-Large : 230 mm min	Medium : 235 mm Large : 237 mm X-Large : 250 mm XX-Large : 238 mm		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the width of the gloves	Medium : 95+/-10 mm Large : 110+/-10 mm X-Large : 120+/-10 mm X-Large : 130+/-10 mm	Medium : 95 mm Large : 113 mm X-Large : 121 mm XX-Large : 129 mm		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the thickness of the gloves	Palm: 0.05 mm min for all sizes Finger: 0.05 mm min for all sizes	**Size**	**Palm**	**Finger**
			Medium	0.077 mm	0.111 mm
			Large	0.106 mm	0.109 mm
			X-Large	0.089 mm	0.115 mm
			XX-Large	0.113 mm	0.107 mm
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 14MPa min for all sizes **After Ageing** Tensile Strength 14MPa min for all sizes	**Size**	**Before ageing**	**After ageing**
			Medium	34.0 MPa	37.3 MPa
	To determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 500% min for all sizes **After Ageing** Ultimate Elongation 400% min for all sizes	**Size**	**Before ageing**	**After ageing**
			Medium	542%	503%
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 2.5		
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	≤ 2 mg/glove	Medium: 0.3516 mg/glove		

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	To determine the breakthrough detection time of chemotherapy drugs	Bleomycin Sulfate 15 mg/ml (15,000 ppm) >240 Minutes	Bleomycin Sulfate 15 mg/ml (15,000 ppm) >240 Minutes
		Busulfan 6 mg/ml (6,000 ppm) >240 Minutes	Busulfan 6 mg/ml (6,000 ppm) >240 Minutes
		Carboplatin 10 mg/ml (10,000 ppm) >240 Minutes	Carboplatin 10 mg/ml (10,000 ppm) >240 Minutes
		Cisplatin 1 mg/ml (1,000 ppm) >240 Minutes	Cisplatin 1 mg/ml (1,000 ppm) >240 Minutes
		Cyclophosphamide 20 mg/ml (20,000 ppm) >240 Minutes	Cyclophosphamide 20 mg/ml (20,000 ppm) >240 Minutes
		Cytarabine 100 mg/ml (100,000 ppm) >240 Minutes	Cytarabine 100 mg/ml (100,000 ppm) >240 Minutes
		Dacarbazine 10 mg/ml (10,000 ppm) >240 Minutes	Dacarbazine 10 mg/ml (10,000 ppm) >240 Minutes
		Daunorubicin HCl 5 mg/ml (5,000 ppm) >240 Minutes	Daunorubicin HCl 5 mg/ml (5,000 ppm) >240 Minutes
		Docetaxel 10 mg/ml (10,000 ppm) >240 Minutes	Docetaxel 10 mg/ml (10,000 ppm) >240 Minutes
		Doxorubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes	Doxorubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes
		Epirubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes	Epirubicin HCl 2 mg/ml (2,000 ppm) >240 Minutes
		Etoposide 20 mg/ml (20,000 ppm) >240 Minutes	Etoposide 20 mg/ml (20,000 ppm) >240 Minutes
		Fludarabine 25 mg/ml (25,000 ppm) >240 Minutes	Fludarabine 25 mg/ml (25,000 ppm) >240 Minutes
		Fluorouracil 50 mg/ml (50,000 ppm) >240 Minutes	Fluorouracil 50 mg/ml (50,000 ppm) >240 Minutes
		Gemcitabine 38 mg/ml (38,000 ppm) >240 Minutes	Gemcitabine 38 mg/ml (38,000 ppm) >240 Minutes
		Idarubicin HCl 1 mg/ml (1,000 ppm) >240 Minutes	Idarubicin HCl 1 mg/ml (1,000 ppm) >240 Minutes
		Ifosfamide 50 mg/ml (50,000 ppm) >240 Minutes	Ifosfamide 50 mg/ml (50,000 ppm) >240 Minutes
		Irinotecan 20 mg/ml (20,000 ppm) >240 Minutes	Irinotecan 20 mg/ml (20,000 ppm) >240 Minutes
		Mechlorethamine HCl 1 mg/ml (1,000 ppm) >240 Minutes	Mechlorethamine HCl 1 mg/ml (1,000 ppm) >240 Minutes
		Melphalan 5 mg/ml (5,000 ppm) >240 Minutes	Melphalan 5 mg/ml (5,000 ppm) >240 Minutes
		Methotrexate 25 mg/ml (25,000 ppm) >240 Minutes	Methotrexate 25 mg/ml (25,000 ppm) >240 Minutes
		Mitomycin C 0.5 mg/ml (500 ppm) >240 Minutes	Mitomycin C 0.5 mg/ml (500 ppm) >240 Minutes
		Mitoxantrone HCl 2 mg/ml (2,000 ppm) >240 Minutes	Mitoxantrone HCl 2 mg/ml (2,000 ppm) >240 Minutes
		Paclitaxel 6 mg/ml (6,000 ppm) >240 Minutes	Paclitaxel 6 mg/ml (6,000 ppm) >240 Minutes
		Rituximab 10 mg/ml (10,000 ppm) >240 Minutes	Rituximab 10 mg/ml (10,000 ppm) >240 Minutes
		Trisenox 1 mg/ml (1,000 ppm) >240 Minutes	Trisenox 1 mg/ml (1,000 ppm) >240 Minutes
		Vincristine Sulfate 1 mg/ml (1,000 ppm) >240 Minutes	Vincristine Sulfate 1 mg/ml (1,000 ppm) >240 Minutes

BIOCOMPATIBILITY DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ISO 10993-23 First edition 2021-01 Biological Evaluation of Medical Devices - Part 23, Tests for Irritation.	To evaluate the local dermal irritation of a test article extract following intracutaneous injection in rabbits.	Under the condition of study not an irritant	Under the conditions of the study, the test article met the requirements of the test
10993-10 Fourth edition 2021-11 Biological Evaluation of Medical Devices - Part 10, Tests for Skin Sensitization.	To evaluate the test item, for the skin sensitization in Guinea pigs by maximization test.	Under the conditions of the study, not a sensitizer	Under the conditions of the study, the test article was not considered a sensitizer
ISO 10993-5 Third edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5, Tests for In Vitro Cytotoxicity.	To determine the potential of a test article to cause cytotoxicity	Under the conditions of the study, non-cytotoxic	The undiluted test article extract and 50% test article extract dilution did not meet the requirements of the test and the 25%, 12.5%, 6.25%, and 3.13% test article extract dilutions met the requirements of the test. The cytotoxic concern was addressed via acute systemic toxicity testing
ISO 10993-11 Third edition 2017-09 Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity.	To evaluate the acute systemic toxicity of a test article extract following injection in mice.	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	Under the conditions of study, there was no mortality or evidence of systemic toxicity

The performance test data of the non-clinical tests that support a determination of safety and equivalence is the same as mentioned above (ASTM Requirements).

The performance test data of the non-clinical tests meet following standards:
ASTM D6319-19 Standard Specification for Nitrile examination Gloves for Medical Application.

ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves.

ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

ISO 10993-23 First Edition 2021-01 Biological Evaluation of Medical Devices - Part 23, Tests for Irritation.

ISO 10993-10 Fourth Edition 2021-11 Biological Evaluation of Medical Devices - Part 10, Tests for Skin Sensitization.

ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5, Tests for In Vitro Cytotoxicity.

ISO 10993-11 Third Edition 2017-09 Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity.

H. CLINICAL TESTING SUMMARY

Not applicable - Clinical data is not needed for gloves.

I. CONCLUSION

The conclusions drawn from the non-clinical test demonstrate that the subject device in 510(K) submission, Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested For Use With Chemotherapy Drugs) is as safe, as effective, and performs as well as or better than the legally marketed predicate device K213440.