March 20, 2020

[redacted] Gloves (Thailand) [redacted]
%[redacted]
[redacted]
[redacted].
[redacted]
[redacted]

Re: K1[redacted]1
Trade/Device Name: Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Lilac, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Orchid, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Oyster
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: November 27, 2019
Received: December 23, 2019

Dear [redacted]:

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 Elizabeth Claverie, M.S.
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)*
K[redacted]1

Device Name

Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Lilac, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Orchid, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Oyster

Indications for Use *(Describe)*

This device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The tested chemotherapy drugs and permeation times are as follows:

Bleomycin Sulfate 15 mg/mL, >240 minutes
Busulfan 6 mg/mL, >240 minutes
Carboplatin (Paraplatin) 10 mg/mL, >240 minutes
Carmustine (BCNU) 3.3 mg/mL, 17.1 minutes
Cisplatin 1.0 mg/mL, >240 minutes
Cyclophosphamide (Cytoxan) 20 mg/mL, >240 minutes
Cytarabine 100 mg/mL, >240 minutes
Dacarbazine (DTIC) 10 mg/mL, >240 minutes
Daunorubicin 5 mg/mL, >240 minutes
Docetaxel 10 mg/mL, >240 minutes
Doxorubicin Hydrochloride 2 mg/mL, >240 minutes
Epirubicin (Ellence) 2 mg/mL, >240 minutes
Etoposide (Toposar) 20 mg/mL, >240 minutes
Fludarabine 25 mg/mL, >240 minutes
Fluorouracil 50 mg/mL, >240 minutes
Gemcitabine 38 mg/mL, >240 minutes
Idarubicin 1 mg/mL, >240 minutes
Ifosfamide 50 mg/mL, >240 minutes
Irinotecan 20 mg/mL, >240 minutes
Mechlorethamine 1 mg/mL, >240 minutes
Melphalan 5 mg/mL, >240 minutes
Methotrexate 25 mg/mL, >240 minutes
Mitomycin C 0.5 mg/mL, >240 minutes
Mitoxantrone 2 mg/mL, >240 minutes
Paclitaxel (Taxol) 6 mg/mL, >240 minutes
Rituximab 10 mg/mL, >240 minutes
Thiotepa 10 mg/mL, 27.9 minutes
Trisenox 1 mg/mL , >240 minutes
Vincristine Sulfate 1 mg/mL, >240 minutes

Fentanyl tested as follows:

Fentanyl citrate 100 mcg/2mL, >240 minutes

WARNING: Not for use 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

K1[redacted]1

[As Required by 21 section 807.92 (c)]

Summary prepared: March 17, 2020

A. APPLICANT INFORMATION

Submitter Name: [redacted] (Thailand) [redacted]d

Address: [redacted]. Thailand 90110

Phone: (+66) [redacted] 663

Fax: (+66) [redacted] 677

Contact Person: Mr. [redacted], Managing Director

B. US AGENT & CONTACT PERSON INFORMATION

Official Correspondent: [redacted].

Address: [redacted]

Phone: +[redacted]

Fax: +1[redacted]

Contact person: [redacted]r

C. DEVICE IDENTIFICATION

Device Trade or Proprietary Name: Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Lilac, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Orchid, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Oyster

Device Common or Usual Name: Examination glove

Device Classification Name: Nitrile Patient Examination Glove (21 CFR 880.6250)

Device Product Codes: LZA, LZC, QDO

Device Class: Class I

D.PREDICATE DEVICE INFORMATION

510(k) Number: K1[redacted]1

Trade Name: Non-sterile, Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy Drugs

Common Name: Examination Glove

Classification Name: Nitrile Patient Examination Glove

Device Product Codes: LZA, LZC, QDO

Device Class: Class I

Regulation Number: 21 CFR 880.6250

E. DESCRIPTION OF THE DEVICE

Non-sterile, Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy Drugs and Fentanyl.

F. INTENDED USE OF THE DEVICE

This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

G. Technological Characteristics Comparison Table

TECHNOLOGICAL CHARACTERISTICS	STANDARD	PREDICATE DEVICE K1[redacted]1	SUBJECT DEVICE K1[redacted]1	COMPARISON
510(k) Number		K1[redacted]1	K1[redacted]1	
Trade Name		Non-sterile, Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy Drugs	Non-sterile, Powder Free Nitrile Examination Gloves	Different
Common Name		Examination Glove	Examination Glove	Identical
Classification Name		Nitrile Patient Examination Glove	Nitrile Patient Examination Glove	Identical
Device Product Codes		LZA, LZC, QDO	LZA, LZC, QDO	Identical
Device Class		Class I	Class I	Identical
Regulation Number		21 CFR 880.6250	21 CFR 880.6250	Identical
Indications for Use	N/A	This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. The tested chemotherapy drugs are as follows: Carmustine (BCNU) Cisplatin, Cyclophosphamide, Dacarbzine (DTIC), Doxorubicin Hydrochloride, Etoposide (Toposar),	This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Bleomycin Sulfate, 15mg/mL, >240 minutes Ifosfamide 50 mg/mL, >240 minutes Busulfan 6mg/mL, >240 minutes Irinotecan 20 mg/mL	Similar

			>240 minutes Carboplatin (Paraplatin) 10 mg/mL, >240 minutes Mechlorethamine 1mg/mL, >240 minutes Carmustine (BCNU) 3.3 mg/mL, 17.1 minutes, 22.8 minutes, and 22.3 minutesminutes Melphalan 5 mg/mL, >240 minutes Cisplatin 1.0 mg/mL, >240 minutes Methotrexate 25 mg/mL, >240 minutes Cyclophosphamide (Cytoxan) 20 mg/mL,	

		Fluorouracil, Methotrexate, Paclitaxel (Taxol), Thiotepa, Vincristine Sulfate Note Carmustine (BCNU) and Thiotepa have low permeation times Fentanyl tested as follows: Fentanyl Citrate	>240 minutes Mitomycin C 0.5 mg/mL, >240 minutes Cytarabine 100 mg/mL, >240 minutes Mitoxantrone 2 mg/mL, >240 minutes Dacarbazine (DTIC) 10 mg/mL, >240 minutes Paclitaxel (Taxol) 6 mg/mL, >240 minutes Daunorubicin 5 mg/mL, >240 minutes Rituximab 10 mg/mL, >240 minutes Docetazel 10 mg/mL, >240 minutes Thiotepa 10 mg/mL, 27.9 minutes Doxorubicin Hydrochloride 2 mg/mL, >240 minutes Trisenox mg/mL, >240 minutes Epirubicin (Ellence) 1 mg/mL, >240 minutes Vincristine Sulfate 1 mg/mL, >240 minutes Etoposide (Toposar) 20 mg/mL, >240 minutes Fludarabine 25 mg/mL, >240 minutes Fluorouracil 50 mg/mL, >240 minutes Gemcitabine 38 mg/mL, >240 minutes Idarubicin 1 mg/mL, >240 minutes WARNING – Not for use with Carmustine and Thiotepa Fentanyl tested as follows: Fentanyl Citrate 100	

			mcg/2mL, >240 minutes	
Dimensions: overall length	ASTM D 6319-10, Minimum 230 mm	238 mm 238 mm 238 mm	238 mm (NOF_SL) 240 mm (NOF_EL) 240 mm (NOF_SD)	Similar
Dimensions: width	ASTM D 6319-10, 110 ± 10 mm	Size Large 114 mm 115 mm 114 mm	Size Large 110 mm 110 mm 111 mm	Similar
Dimensions: palm and finger thickness	ASTM D 6319-10, Minimum 0.05 mm	Palm 0.07 mm 0.07 mm 0.07 mm Finger 0.07 mm 0.08 mm 0.09 mm	Palm 0.05mm (NOF_SL) 0.05mm (NOF_EL) 0.10 mm (NOF_SD) Finger 0.08 mm (NOF_SL) 0.08 mm (NOF_EL) 0.14 mm (NOF_SD)	Similar
Tensile strength: before and after aging	ASTM D 6319-10	Before 35 MPa 33 MPa 35 MPa After 31 MPa 32 MPa 34 MPa	Before 34 MPa (NOF_SL) 37 MPa (NOF_EL) 33 MPa (NOF_SD) After 38 MPa (NOF_SL) 41 MPa (NOF_EL) 37 MPa (NOF_SD)	Similar
Ultimate elongation: before and after aging	ASTM D 6319-10	Before 538% 534% 535% After 518% 493% 503%	Before 570 (NOF_SL) 564% (NOF_EL) 630% (NOF_SD) After 535% (NOF_SL) 551% (NOF_EL) 625% (NOF_SD)	Similar
Powder Free Residue	ASTM D 6319-10	0.7 mg/glove 0.8 mg/glove 0.8 mg/glove	0.3 mg/glove (NOF_SL) 0.5 mg/glove (NOF_EL) 0.5 mg/glove (NOF_SD)	Similar
Biocompatibility	ISO 10993-10 Primary Skin Irritation in Rabbits	Under the conditions of the study, the polar and non- polar device extracts were found not to be an irritant to the animal model.	Under the conditions of the study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Same
	ISO 10993-5 In vitro cytotoxicity	Cytotoxic	Cytotoxic	Same

	ISO 10993-11 Tests for systemic toxicity	the device extracts did not elicit a systemic response in the animal model.	the device extracts did not elicit a systemic response in the animal model.	Same
	ISO 10993-10 Guinea Pig Sensitization	Under the conditions of the study, the polar and non- polar device extracts were found not to be sensitizers to the animal model.	Under the conditions of the study, the polar and non-polar device extracts were found not to be sensitizers to the animal model.	Same

H. Summary of Non-Clinical Performance Testings

Non-clinical tests were conducted to demonstrate that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

Measurement	Standard Criteria	Subject Device Model	Results
Tensile strength per ASTM D 6319-10			
Before aging	14 MPa Min	Model – NOF_SD Orchid	33
		Model – NOF_SL Lilac	34
		Model – NOF_EL Oyster	37
After aging (70C, 168hrs.)	14 MPa Min	Model – NOF_SD Orchid	37
		Model – NOF_SL Lilac	38
		Model – NOF_EL Oyster	41
Ultimate elongation per ASTM D 6319-10			
Before aging	500% Min	Model – NOF_SD Orchid	630
		Model – NOF_SL Lilac	570
		Model – NOF_EL Oyster	564
After aging (70C, 168hrs.)	400% Min	Model – NOF_SD Orchid	625
		Model – NOF_SL Lilac	535
		Model – NOF_EL Oyster	551
Length (mm)	230 mm Min (M)	Model – NOF_SD Orchid	240 mm
		Model – NOF_SL Lilac	238 mm
		Model – NOF_EL Oyster	240 mm
Thickness(mm) Single wall Finger	0.05 mm Min	Model – NOF_SD Orchid	0.14
		Model – NOF_SL Lilac	0.08
		Model – NOF_EL Oyster	0.08
Thickness (mm) Single wall Palm	0.05 mm Min	Model – NOF_SD Orchid	0.10
		Model – NOF_SL Lilac	0.06
		Model – NOF_EL Oyster	0.05
Width	110+/-10 mm (M)	Model – NOF_SD Orchid	111
		Model – NOF_SL Lilac	110
		Model – NOF_EL Oyster	110
Freedom from holes per ASTM D5151-2006			
Freedom from holes	GI, AQL 2.5 Accept – 7 Reject – 8	Model – NOF_SD Orchid: 125	0
		Model – NOF_SL Lilac: 125	1
		Model – NOF_EL Oyster: 125	1
Powder Residue, ASTM D6124-2006			
Powder Residue	2.0 mg/glove	Model – NOF_SD Orchid	0.5 mg/glove
		Model – NOF_SL Lilac	0.3 mg/glove
		Model – NOF_EL Oyster	0.5 mg/glove
Resistance of Medical Gloves to Permeation by Chemotherapy Drugs per ASTM D6978			

Test Drug and Concentration	Minimum Breakthrough Detection Time Model – NOF_SD Orchid	Minimum Breakthrough Detection Time Model – NOF_SL Lilac	Minimum Breakthrough Detection Time Model – NOF_EL Oyster	Steady State Perm. Rate
Bleomycin Sulfate 15,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Busulfan 6,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Carboplatin 10,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Carmustine (BCNU) 3,300 ppm	17.1 minutes	22.8 minutes	22.3 minutes	0.4 0.4 0.3
Cisplatin 1,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Cytoxan 20,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Cytarabine 100,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
DTIC 10,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Daunorubicin 2,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Docetaxel 10,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Doxorubicin hydrochloride 2,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Epirubicin 2,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Etoposide (Toposar) 20,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Fludarabine 25,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Fluorouracil 50,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Gemcitabine 38,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Idarubicin 1,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Ifosfamide 50,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Irinotecan 20,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Mechlorethamine 1,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Melphalan 5,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Methotrexate 25,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Mitomycin C 500 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Mitoxantrone 2,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A

Taxol 6,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Rituximab 10,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Thiotepa 10,000 ppm	27.9 minutes	39.1 minutes	39 minutes	0.3 0.3 0.2
Trisenox 1,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Vincristine fulfate 1,000 ppm	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A
Fentanyl Citrate 100 mcg/2mL	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	N/A

The test results demonstrated that the proposed device complies with following standards:

ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D5151-2006 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves
ASTM D6124-2006 (Reapproved 2001) Standard Test Method for Residual Powder on Medical Gloves
ASTM D6978 – Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
ASTM D412-2006a (reapproved 2013) Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension
ASTM D573-2004 (Reapproved 2010) Standard Test Method for Rubber-Deterioration in an Air Oven
ASTM D3767-03 Standard Practice for Rubber-Measurement of Dimensions
ISO 2859 Sampling Procedures and Tables for Inspection by Attributes

- Tested according to ASTM D5151 for pinholes and freedom from holes, Inspection Level: GI, AQL = 2.5
- Tested according to ASTM D6124 for powder residue, Inspection Level: N =5, AQL = N/A
- Tested according to ASTM D412 for tensile strength and ultimate elongation before and after aging, Inspection Level: S-2, AQL 4.0
- Tested according to ASTM D3767 for length, thickness, and width, Inspection Level: S-2, AQL 4.0

ISO 10993-5 Biological evaluation of medical devices-Part5 Tests for in vivo cytotoxicity Minimal Essential Media Elution Test:
ISO 10993-10 Biological evaluation of medical devices-Part 10 Test for irritation and delayed-type hypersensitivity

ISO 10993-11 Biological evaluation of medical devices-Part 11 Tests for systemic toxicity Acute Systemic Toxicity Test.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that Non-Sterile, Powder Free Nitrile

Exam Glove Tested for use with Chemotherapy Drugs - Lilac, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Orchid, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs – Oyster are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K1[redacted]1.