BLUZEN

Nitrile Examination Gloves

FINISHED PRODUCT ATTRIBUTES

The finished gloves shall exhibit uniform appearance in terms of size, shape and color, and possess good quality in terms of finished texture, typical of the product and the form of processing.

100 Gloves per Box

Inner Box Dimensions:
21.5 x 12.2 x 6 cm

Carton Dimensions: 31.5 x 25.4 x 23 cm

CARTON WEIGHTS		
SIZE	**NET WEIGHT**	**GROSS WEIGHT**
S	**3.7kg**	**4.5kg**
M	**4.2kg**	**4.9kg**
L	**4.6kg**	**5.3kg**
XL	**5.0kg**	**5.7kg**

DESCRIPTION	UPC	GTIN
BluZen - Medical Nitrile Black Powder-free - Small	810676034359	08106760343592
BluZen - Medical Nitrile Black Powder-free - Medium	810676034366	08106760343660
BluZen - Medical Nitrile Black Powder-free - Large	810676034373	08106760343738
BluZen - Medical Nitrile Black Powder-free - X-Large	810676034380	08106760343806

SPECIFICATIONS

Product: Disposable Nitrile Glove, Extra Strong, Powder-free
Allergy Information: Allergy friendly and Latex-free
Touch and Feel: Soft, pliable feel with good fit
Waterproof: Yes
Uses: Suitable for a wide variety of industries (e.g., Clinics, Dental, Hospital, Homecare, Lab, Food, Housing, IT Industries, Beauty Industries)
Color: Black
Sterility: Non-sterile
Shelf Life: 5-year shelf life with appropriate storage conditions
Features: Ambidextrous and Finger Textured
MIL: 6 (.15mm +/- .01mm)

SIZE	LENGTH (MM)	WIDTH (MM)	THICKNESS	
			FINGERTIP	PALM
S	243	85	.15	.09
M	249	96	.15	.09
L	246	106	.15	.09
XL	248	115	.15	.09

FDA LETTER

November 15, 2017

[redacted]

Re: K171873
Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: October 13, 2017
Received: October 13, 2017

Dear Da Shi:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

FDA LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171873

Device Name

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*

A 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.

These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) 3.3 mg/ml	14.7
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10.0 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Etoposide (Toposar) 20.0 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Ifosfamide 50.0 mg/ml	>240
Methotrexate 25 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2.0 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Thiotepa 10.0 mg/ml	58.8
Vincristine Sulfate 1.0 mg/ml	>240

Please note the following drugs have extremely low permeation times: Carmustine (BCNU) (3.3mg/ml) 14.7 minutes and Thiotepa (10 mg/ml) 58.8 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.

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

Preparation Date: Nov. 8th, 2017

Name of the Device:

Device trade or proprietary name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs
Device common or usual name: Patient Examination Glove
Device Classification Name: LZA - Polymer Patient Examination Glove
Device Classification Name: LZC - Patient Examination Glove, Specialty
Regulation Number: 21 CFR 88.6250
FDA Device Class: Class 1
Product Code: LZA, LZC

Predicate Device:

Class I patient Examination glove and tested for use with Chemotherapy Drugs, Powder Free, LZC, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.

Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs
Copmany Name: Kossan International Sdn. Bhd.
510(K) Number: K151750

Device Description:

The subject device in this 510(k) Notification is a Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

The subject device is a patient examination glove made from nitrile compound, blue in color, powder free and non-sterile (as per 21 CFR 880.6250, class I).

The principle operation of the medical device to provide single use barrier protection for the wearer and the device meets all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

Intended use of the Device (Indication for use)

A 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.
These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) 3.3 mg/ml	14.7
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10.0 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Etoposide (Toposar) 20.0 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Ifosfamide 50.0 mg/ml	>240
Methotrexate 25 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2.0 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Thiotepa 10.0 mg/ml	58.8
Vincristine Sulfate 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) 14.7 minutes and Thiotepa 58.8 minutes.

Summary of the Technological Characteristics of the Device:

The subject device is summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 6319-10	Meets
Physical Properties	ASTM standard D 6319-10	Meets
Freedom from pinholes	21 CFR 800.20 ASTM D5151-11	Meets
Powder Residual	ASTM D6319-10 and D6124-06(Reapproved 2011)	Meets
Biocompatibility	Primary Skin Irritation ISO 10993-10:2010	Not a primary skin irritant under the conditions of the study
	Dermal sensitization in the guinea pig ISO 10993-10:2010	Not a contact sensitizer under the conditions of the study

Substantial Equivalence Based on Assessment of Non-Clinical Performance Data

Bench tests were conducted to verify that the proposed device met all specifications and the proposed device is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical application.
ASTM D5151-06 (2011), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (2011), Standard Test Method for Residual Powder on Medical Gloves.
ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs

The subject device meets the same test standards conducted by the predicate device. Both device has the same sizes, color, physical and dimensional characteristics.

The minimum breakthrough detection time of Carmustine for the subject device is below 30 minutes, similar with predicate K151750 (Blue).

The minimum breakthrough detection time of Thiotepa for the subject device is at 58.8 minutes. The subject device is having longer permeation time than predicate K151750 (Blue).

Warning statement (Do Not Use with Carmustine and Thiotepa) for subject device is included in Labeling, similar with predicate device.

The subject device has similar thickness with predicate K151750 at palm, and similar length with predicate K151750 (Blue).

The subject device is having identical specification with predicate K151750 (Blue) with thickness at minimum 0.05mm and length at minimum 230mm.

The difference in labeling with additional drugs tested do not affect the safety and effectiveness of the subject device.

The subject device and the predicate device K151750 (Blue) share the same intended use, same Nitrile material, same compliance with ASTM standards. There is no difference between the subject device and the predicate device K151750 (Blue) with respect to intended use, non-clinical performance data and technological characteristics.

Consequently, the gloves that are the subject of this submission are substantially equivalent to a legally marketed glove K151750 (Blue).

Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for this submission.

Biocompatibility

Biocompatibility tests indicated that under the conditions of the studies, the gloves were non-sensitizing and non-irritating.

Legally Marketed Device to which Substantial Equivalence is Claimed

The legally marketed predicate device in scope is as follows:

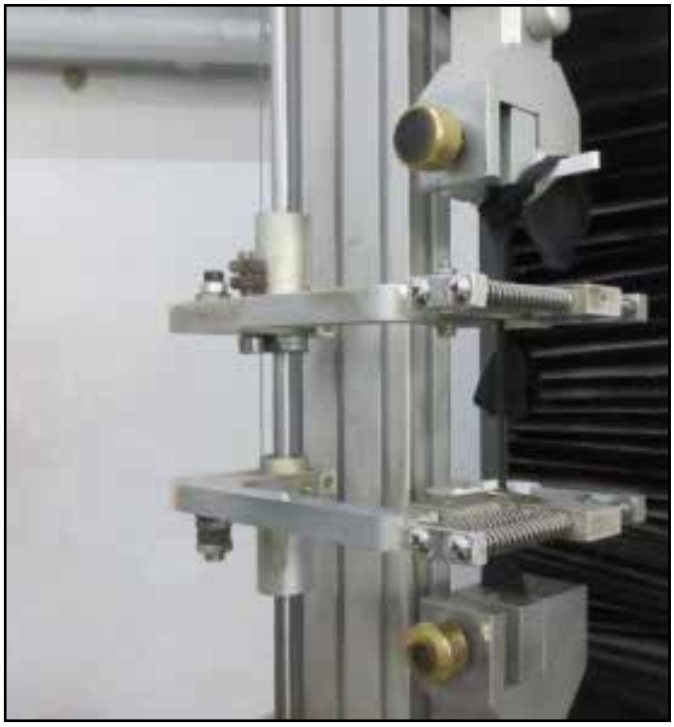
K151750 - Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile

TEST REPORT IMAGES

Glove Count

Water Leakage Check

Water Leakage Test



Elongation Check

TEST REPORT

TESTCOO **INSPECTION REPORT** Report Date: 28-Dec-2021

Inspection Section

	
Black	Black

General Information

Buyer Name	Remcoda LLC	**P.O. Number**	REM11021NT
Vendor	Zhonghong Pulin Medical Products Co.,Ltd.	**Item Number**	N/A
Inspection Date	2021-12-27	**Product Name**	NITRILE EXAM DISPOSABLE GLOVES, BLUE, 4.0G,NITRILE EXAM DISPOSABLE GLOVES, BLACK, 4.0G
Inspection Location	Luannan Country, Tangshan City, Hebei Province, PRC	**Total Shipment Quantity**	16500000
Inspection Type	Final Random Inspection (FRI)	**Combined Sampling**	Yes
Inspection Reference	Contract		

Inspection Results

OVERALL CONCLUSION	**Not Conform**	Remark 4
A.Visual And Workmanship	**Conform**	N/A
B.Quantity Conformity	**Conform**	N/A
C.Packing / Marking / Labeling	**Conform**	3
D.Product Conformity	**Pending**	1
E.Data Measurement / Field Test	**Not Conform**	2, 4

Remark
1. No approval or reference sample was available on site.
2. No SPEC. for product size, weight and thickness on data measurement from client, and inspector record the actual finding.
3. There is no PO number on CTN.
4. For item-Blue, S and M barcode on master CTN cannot be readable on site.

TEST REPORT

TESTCOO **INSPECTION REPORT** Report Date: 28-Dec-2021

Unit view-M

CTN front mark-L

CTN side mark-L

Zoom in

Color box top-L

Color box bottom-L

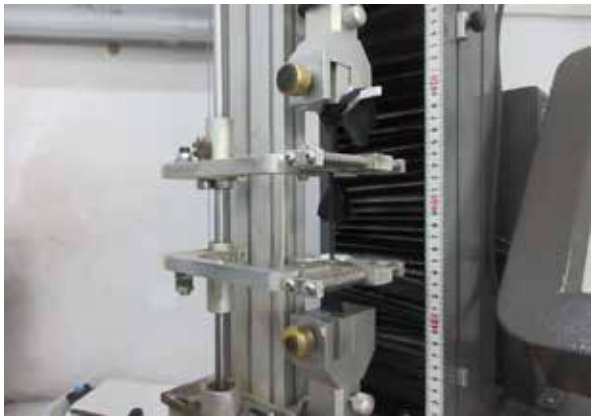
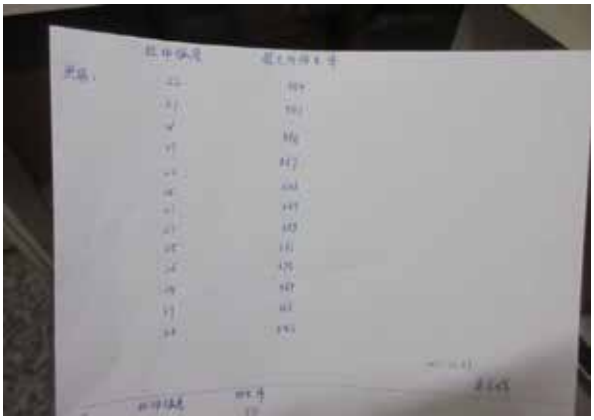
TEST REPORT

TESTCOO **INSPECTION REPORT** Report Date: 28-Dec-2021

	
Zoom in	Side mark-L
	
Unit view-L	100 pcs per box-L
	
CTN front mark-XL	CTN side mark-XL

TEST REPORT

TESTCOO **INSPECTION REPORT** Report Date: 28-Dec-2021

	
Water leakage test	Elongation check
	
Elongation check	Elongation check
	
TDC	N/A