



December 8, 2021

Jiangsu Nanfang Medical Co., Ltd
Johnson Liu
Consultant
CNMED Consultant
31 Archer St
Upper MT Gravatt, QLD 4122
Australia

Re: K212639

Trade/Device Name: Disposable Medical Nitrile Examination Gloves (Non sterile)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZC, LZA
Dated: November 8, 2021
Received: November 12, 2021

Dear Johnson Liu:

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, PhD
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

Indications for Use

510(k) Number (if known)
K212639

Device Name
Disposable Medical Nitrile Examination Gloves (Non Sterile)

Indications for Use (Describe)

Disposable Medical Examination Nitrile Gloves (Non Sterile) are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

In addition, these patient examination gloves were tested for use with the following drug concentrations per ASTM D6978-05(2019):

The following drugs had NO breakthrough detected up to 240 minutes:

Busulfan, 6 mg/ml (6,000 ppm)	Fluorouracil, 50.0 mg/ml (50,000 ppm)
Carboplatin /Paraplatin, 10 mg/ml (10,000 ppm)	Ifosfamide, 50 mg/ml (50,000 ppm)
Cisplatin, 1.0 mg/ml (1,000 ppm)	Mechlorethamine HCl, 1 mg/ml (1,000 ppm)
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Methotrexate, 25 mg/ml (25,000 ppm)
Cytarabine HCl, 100 mg/ml (100,000 ppm)	Mitomycin, 0.5 mg/ml (500 ppm)
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Mitoxantrone, 2 mg/ml (2,000 ppm)
Docetaxel, 10 mg/ml (10,000 ppm)	Paclitaxel, 6.0 mg/ml (6,000 ppm)
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Vincristine Sulfate, 1 mg/ml (1,000 ppm)
Etoposide, 20.0 mg/ml (20,000 ppm)	

Please note that the following drug has low permeation times of less than 60 minutes:

Carmustine (BCNU) 3.3 mg/ml (3,300 ppm), 44.7minutes

ThioTepa 10.0 mg/ml (10,000 ppm), 35.7 minutes

WARNING: Do not use Carmustine and 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

Disposable Medical Nitrile Examination Gloves (Non sterile)

Preparation Date: November 8th, 2021

1. SUBMITTER

Company Name: Jiangsu Nanfang Medical Co.,Ltd

Company Address: No.1 Guoxiang RD. Wujin Economic Development Zone, WUJIN CHANGZHOU Jiangsu, CN 213149

Contact Person: Johnson Liu

Telephone Number: +614-0158-9995

Email: Johnson@cnmed.com.au

2. NAME OF THE DEVICE

Trade Name / Proprietary Name: Disposable Medical Nitrile Examination Gloves (Non sterile)

Device Name: Disposable Medical Examination Nitrile Gloves

Device Classification Name: Patient Examination Gloves

Device Class: Class I

Device Classification Number: 21 CFR 880.6250

Product Code: LZC LZA

3. IDENTIFICATION OF THE LEGALLY MARKETED DEVICE

Predicate Device: K172525

Applicant: Central Medicare Sdn. Bhd

Device Name: Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs

Device Classification Name: Patient Examination Gloves Device

Classification Number: 21 CFR 880.6250

Device Class: Class I

Product Code: LZC LZA

Review Panel: General Hospital

4. DEVICE DESCRIPTION

The subject device in this 510(k) Notification is Disposable Medical Nitrile Examination Gloves (Non sterile), a patient examination glove made from nitrile compound, blue color, powder free and non-sterile (Per 21 CFR 880.6250, Class I). The device meets the specifications in ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application* and tested as per ASTM D6978 *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*.



5. INDICATIONS for USE OF THE DEVICE

Disposable Medical Nitrile Examination Gloves (Non sterile) are a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

In addition, these patient examination gloves were tested for use with the following drug concentrations per ASTM D6978-05(2019):

The following drugs had NO breakthrough detected up to 240 minutes:

Busulfan, 6 mg/ml (6,000 ppm)	Fluorouracil, 50.0 mg/ml (50,000 ppm)
Carboplatin /Paraplatin, 10 mg/ml (10,000 ppm)	Ifosfamide, 50 mg/ml (50,000 ppm)
Cisplatin, 1.0 mg/ml (1,000 ppm)	Mechlorethamine HCl, 1 mg/ml (1,000 ppm)
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Methotrexate, 25 mg/ml (25,000 ppm)
Cytarabine HCl, 100 mg/ml (100,000 ppm)	Mitomycin, 0.5 mg/ml (500 ppm)
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Mitoxantrone, 2 mg/ml (2,000 ppm)
Docetaxel, 10 mg/ml (10,000 ppm)	Paclitaxel, 6.0 mg/ml (6,000 ppm)
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Vincristine Sulfate, 1 mg/ml (1,000 ppm)
Etoposide, 20.0 mg/ml (20,000 ppm)	

Please note that the following drug has low permeation times of less than 60 minutes:

Carmustine (BCNU) 3.3 mg/ml (3,300 ppm), 44.7 minutes

ThioTepa 10.0 mg/ml (10,000 ppm), 35.7 minutes

WARNING: Do not use Carmustine and Thiotepa

6. TECHNOLOGICAL CHARACTERISTIC COMPARISON FOR THE PROPOSED AND PREDICATE DEVICES

CHARACTERISTICS	DEVICE PERFORMANCE		REMARKS
	SUBJECT	PREDICATE	
510(k) Number	K212639	K172525	-
Device Name	Disposable Medical Nitrile Examination Gloves (Non sterile)	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	-
Product Code	LZC LZA	LZC LZA	Same
Indications for Use	Disposable Medical Nitrile Examination Gloves (Non sterile) are a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Chemotherapy Drugs Permeation Claim	Busulfan, Carboplatin /Paraplatin, Cisplatin, Cyclophosphamide (Cytosan), Cytarabine HCl, Dacarbazine, Docetaxel, Doxorubicin HCl, Etoposide, Fluorouracil, Ifosfamide, Mechlorethamine HCl, Methotrexate, Mitomycin, Mitoxantrone, Paclitaxel, Vincristine Sulfate.	Fluorouracil,,Etoposide (Toposar), Cyclophosphamid (Cytosan), Carmustine (BCNU), Thiotepa,Paclitaxel (Taxol),Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin, Ifosfamide, Mitoxantrone, Vincristine Sulfate	Equivalent
Materials of Use (ASTM D6910/D6910M-19)	Nitrile compound	Nitrile compound	Same
Color	Blue	Blue	Same
Texture	Finger Textured	Finger Textured	Same
Size (ASTM D6319-19)	Small, Medium, Large,	Small, Medium, Large, Extra Large	Same
Sterilization	Non-sterile	Non-sterile	Same
Usage	Single usage	Single usage	Same
Dimensions (ASTM D6319-19)	Length Min. 220 min Width Min 80+/-10 mm (for small size) Length Min. 230 min Width Min 95+/-10 mm (for medium size) Length Min. 230 min Width Min 110+/-10 mm (for large size)	Length Min. 230 min Width Min 80+/-10 mm (for small size) Length Min. 230 min Width Min 95+/-10 mm (for medium size) Length Min. 230 min Width Min 110+/-10 mm (for large size)	Equivalent

Physical Properties (ASTM D6319-19)	Before Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 500%	Before Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 500%	Same
	After Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	After Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	
Thickness (ASTM D6319-19)	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.08 mm Finger min 0.10 mm	Equivalent
Powder Free (ASTM D6319-19)	≤2 mg/glove	≤0.52 mg/glove	Equivalent
Freedom from Holes (Water Tight -1000 ml) – ASTM D6319-19 (Cross Reference D5151)	AQL 2.5 Passed	AQL 2.5 Passed	Same
Biocompatibility - SKIN SENSITIZATION - ISO 10993-10: 2010 (E)	Under the conditions of study not a sensitizer	Under the conditions of study not a sensitizer	Same
Biocompatibility - SKIN IRRITATION - ISO 10993-10: 2010 (E)	Under the conditions of the study not an irritant	Under the conditions of the study not an irritant	Same
Biocompatibility - <i>IN VITRO</i> CYTOTOXICITY - ISO 10993-5: 2009(E)	Under the conditions of the cytotoxicity study, mild Systemic cytotoxicity (Grade 2) observed. It complied with the criteria in ISO 10993-5:2009.	No information provided	Equivalent
Manufacturer(s)	Jiangsu Nanfang Medical Co.,Ltd	Central Medicare Sdn. Bhd	-----

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods. Both devices meet the ASTM standard D6319-19 and tested for the use with chemotherapy drugs.

7. NON-CLINICAL TESTING SUMMARY

PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria		Result
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Dimensions Test	To determine the width, length, and thickness of the gloves	Size Small	Width: 80 mm \pm 10mm Length: 220 mm (Minimum) Thickness: Finger -0.05 mm (Minimum) Palm -0.05 mm (Minimum)	Width: 82mm-89mm Length 230mm (Minimum) Thickness Finger 0.12mm (Minimum) Palm 0.08mm (Minimum) Passed
		Size Medium	Width: 95 mm \pm 10mm Length: 230 mm (Minimum) Thickness: Finger -0.05 mm (Minimum) Palm -0.05 mm (Minimum)	Width: 91mm-96mm Length 240mm (Minimum) Thickness Finger 0.13mm (Minimum) Palm 0.08mm (Minimum) Passed
		Size Large	Width: 110 mm \pm 10mm Length: 230 mm (Minimum) Thickness: Finger -0.05 mm (Minimum) Palm -0.05 mm (Minimum)	Width: 111mm-113mm Length 240mm (Minimum) Thickness Finger 0.13mm (Minimum) Palm 0.09mm (Minimum) Passed

ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Requirements Test	To determine the tensile strength and ultimate elongation before and after acceleration aging	Before Acceleration Aging: Tensile Strength (MPa): 14 (Minimum) Ultimate Elongation (%): 500 (Minimum) After Acceleration Aging: Tensile Strength (MPa): 14 (Minimum) Ultimate Elongation (%): 400 (Minimum)	Before Acceleration Aging: Tensile Strength (MPa): 29 (Minimum) Ultimate Elongation (%): 515 (Minimum) After Acceleration Aging: Tensile Strength (MPa): 26 (Minimum) Ultimate Elongation (%): 511 (Minimum) Passed
ASTM D6319-19 (ASTM D5151-11) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	(Mean) AQL 2.5	Passed
ASMT D6319-19 (ASTM D6124-11) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	≤ 2.0 mg/glove	0.2 mg/glove, Passed

Testing with Chemotherapy Drugs as per ASTM D6978-05.

The following drugs had NO breakthrough detected up to 240 minutes:

Busulfan, 6 mg/ml (6,000 ppm)	Fluorouracil, 50.0 mg/ml (50,000 ppm)
Carboplatin /Paraplatin, 10 mg/ml (10,000 ppm)	Ifosfamide, 50 mg/ml (50,000 ppm)
Cisplatin, 1.0 mg/ml (1,000 ppm)	Mechlorethamine HCl, 1 mg/ml (1,000 ppm)
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Methotrexate, 25 mg/ml (25,000 ppm)
Cytarabine HCl, 100 mg/ml (100,000 ppm)	Mitomycin, 0.5 mg/ml (500 ppm)
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Mitoxantrone, 2 mg/ml (2,000 ppm)
Docetaxel, 10 mg/ml (10,000 ppm)	Paclitaxel, 6.0 mg/ml (6,000 ppm)
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Vincristine Sulfate, 1 mg/ml (1,000 ppm)
Etoposide, 20.0 mg/ml (20,000 ppm)	

The drugs have low permeation times of less than 60 minutes:

Carmustine (BCNU) 3.3 mg/ml (3,300 ppm), 44.7minutes

ThioTepa 10.0 mg/ml (10,000 ppm), 35.7 minutes

BIO-COMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the potential of the material under test to produce skin irritation in rabbits	Under the condition of study not an irritant	Under the condition of study not an irritant
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the skin sensitization potential of the material both in terms of induction and elicitation in guinea pigs.	Under the conditions of the study not a sensitizer.	Under the conditions of the study not a sensitizer.
ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method	Under the conditions of study, no more than grade 2 cytotoxic reaction	Slight (Grade 1) cytotoxicity reaction observed.

8. CLINICAL TESTING SUMMARY

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9. CONCLUSION

The conclusions drawn from the non-clinical test demonstrate that the subject device in 510(k) submission, the Disposable Medical Nitrile Examination Gloves (Non Sterile) is as safe, as effective, and performs as well as or better than the legally marketed predicate device K172525- Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs.