October 12, 2024

Nb Medical Company Limited
℅ Wendy Huang
Technical Manager
Wenzhou ThiWe Business Consulting Co., Ltd.
Room 1203, Building C, Hua'ou Jiayuan, No.50 Tangjiaqiao
South Road, Longwan District
Wenzhou, Zhejiang 325000
China

Re: K242812
Trade/Device Name: 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: August 12, 2024
Received: September 18, 2024

Dear Wendy Huang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bifeng Qian -S

Bifeng Qian, M.D, Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242812

Device Name
NITRILE EXAMINATION GLOVES (Tested For Use With Chemotherapy Drugs)

Indications for Use *(Describe)*
NITRILE EXAMINATION GLOVES (Tested For Use With Chemotherapy Drugs) is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05(2023) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes, and can be used with the device.
Cyclophosphamide (20.0 mg/ml)
Doxorubicin HCl (2.0 mg/ml)
Etoposide (20.0 mg/ml)
Fluorouracil (50.0 mg/ml)
Paclitaxel (6.0 mg/ml)
Cisplatin (1.0 mg/ml)
Dacarbazine (10.0 mg/ml)

The following chemotherapy drugs have low permeation times:
Carmustine (3.3 mg/ml): 15 minutes
ThioTEPA (10.0 mg/ml): 97 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.

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.

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510(k) Summary

K242812

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter Information

· Company Name: NB MEDICAL COMPANY LIMITED

· Address: Tay An Industrial Cluster, Tien Hai Town, Tien Hai District, Thai Binh Province, Vietnam

· Phone Number: +84-934-388877

· Contact: VU THI VINH

2.0 Designated Submission Correspondent

· Company Name: Wenzhou ThiWe Business Consulting Co., Ltd.

· Address: Room 1203, Building C, Hua'ou Jiayuan, No.50 Tangjiaqiao South Road, Longwan District, Wenzhou, Zhejiang, 325000, CHINA

· Phone Number: 86-577-88201260

· Contact: Ms. Wendy Huang

· Email: thiwe_reg@outlook.com

3.0 Date of Preparation: October 3, 2024

4.0 Device Information

· Trade/Device Name: NITRILE EXAMINATION GLOVES (Tested For Use With Chemotherapy Drugs)

· Model(s): S, M, L, XL (Blue)

· Common Name: Patient Examination Gloves (Tested For Use With Chemotherapy Drugs)

· 510(k) Number: K242812

5.0 Classification

· Device: Polymer Patient Examination Glove & Medical Glove, Specialty & Medical Gloves With Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs

· Regulation Description: Non-powdered patient examination glove.

· Review Panel: General Hospital

· Product Code: LZA, LZC, OPJ

· Submission Type: 510(k)

· Regulation Number: 21 CFR 880.6250

· Device Class: 1

6.0 Predicate Device Information

· Device Name: NITRILE EXAMINATION GLOVES

· 510(k) Number: K220343

· Manufacturer: NB Medical Co., LTD (i.e. NB MEDICAL COMPANY LIMITED)

7.0 Device Description

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 D6978-05(2023). They are made from Nitrile (NBR). These gloves are blue in color and are powder free. The product is non-sterile, ambidextrous and single use only. NITRILE EXAMINATION GLOVES (Tested For Use With Chemotherapy Drugs) are offered in different sizes: S/M/L/XL.

8.0 Indications for Use

NITRILE EXAMINATION GLOVES (Tested For Use With Chemotherapy Drugs) is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05(2023) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes, and can be used with the device.

Cyclophosphamide (20.0 mg/ml)

Doxorubicin HCl (2.0 mg/ml)

Etoposide (20.0 mg/ml)

Fluorouracil (50.0 mg/ml)

Paclitaxel (6.0 mg/ml)

Cisplatin (1.0 mg/ml)

Dacarbazine (10.0 mg/ml)

The following chemotherapy drugs have low permeation times:

Carmustine (3.3 mg/ml): 15 minutes

ThioTEPA (10.0 mg/ml): 97 minutes

Warning: Not for Use with: Carmustine, ThioTEPA

9.0 Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1: Comparison Table for Subject and Predicate Device

Item	Subject Device (K242812)	Predicate Device (K220343)	Comparison
General Comparison			
Product Code	LZA, LZC, OPJ	LZA	Different Analysis 1
Regulation No.	21 CFR880.6250	21 CFR880.6250	Same
Class	1	1	Same
Intended Use/Indications for Use	NITRILE EXAMINATION GLOVES (Tested For Use With Chemotherapy Drugs) is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05(2023) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy	NITRILE EXAMINATION GLOVES is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	Different Analysis 1

	Drugs.		
Material	Nitrile	Nitrile	Same
Powder Free	Yes	Yes	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Blue	White/Cobalt Blue/Black/Blue	Different Analysis 2
Size	S/M/L/XL	S/M/L/XL	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
Rx Only or OTC	OTC	OTC	Same
Chemotherapy Drugs Claim	The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes, and can be used with the device. Cyclophosphamide (20.0 mg/ml) Doxorubicin HCl (2.0 mg/ml) Etoposide (20.0 mg/ml) Fluorouracil (50.0 mg/ml) Paclitaxel (6.0 mg/ml) Cisplatin (1.0 mg/ml) Dacarbazine (10.0 mg/ml)	No chemotherapy drugs claim	Different Analysis 1

	The following chemotherapy drugs have low permeation times: Carmustine (3.3 mg/ml): 15 minutes ThioTEPA (10.0 mg/ml): 97 minutes Warning: Not for Use with: Carmustine, ThioTEPA		
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, applicable chemotherapy drugs and the minimum breakthrough time	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile	Different Analysis 1
Technological Characteristic and Biocompatibility Comparison			
Dimensions - Length	S: ≥220mm M/L/XL: ≥230mm Meet the requirement of ASTM D6319-19	S: ≥220mm M/L/XL: ≥230mm Meet the requirement of ASTM D6319-19	Same
Dimensions - Width	S: 80±10 mm M: 95±10 mm L: 110±10 mm XL: 120±10 mm	S: 80±10 mm M: 95±10 mm L: 110±10 mm XL: 120±10 mm	Same

	Meet the requirement of ASTM D6319-19	Meet the requirement of ASTM D6319-19	
Physical Properties - Tensile Strength	before aging ≥14 Mpa after aging ≥14 Mpa Meet the requirement of ASTM D6319-19	before aging ≥14 Mpa after aging ≥14 Mpa Meet the requirement of ASTM D6319-19	Same
Physical Properties - Ultimate Elongation	before aging ≥500 % after aging ≥400 % Meet the requirement of ASTM D6319-19	before aging ≥500 % after aging ≥400 % Meet the requirement of ASTM D6319-19	Same
Thickness	Palm: ≥0.05 mm Finger: ≥0.05 mm Meet the requirement of ASTM D6319-19	Palm: ≥0.05 mm Finger: ≥0.05 mm Meet the requirement of ASTM D6319-19	Same
Powder Free Residue	≤2.0mg per glove Meet the requirement of ASTM D 6124 following ASTM D6319-19	≤2.0mg per glove Meet the requirement of ASTM D 6124 following ASTM D6319-19	Same
Freedom from holes	Be free from holes when tested in accordance with ASTM D5151 following ASTM D6319-19 AQL=2.5	Be free from holes when tested in accordance with ASTM D5151 following ASTM D6319-19 AQL=2.5	Same
Biocompatibility	ISO 10993-5 Under conditions of the study, device extract is cytotoxic	ISO 10993-5 Under conditions of the study, device extract is cytotoxic	Same

	ISO 10993-10 Under the conditions of the study, not an irritant or a sensitizer	ISO 10993-10 Under the conditions of the study, not an irritant or a sensitizer	Same
	ISO 10993-11 Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	ISO 10993-11 Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	Same

Analysis 1: The subject device has different indications for use to the predicate device, which results in different product codes, that is, the subject device has extra applicable product codes compared with the predicate device. The major difference between the two devices is that the subject device is claimed for use with certain chemotherapy drugs, while the predicate device did not. However, such difference has been tested according to FDA recognized standard - ASTM D6978-05(2023) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs, which ensures that the subject device will be as safe as for use as the predicate device. Meanwhile, chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling, so this different will not bring new concerns regarding safety and effectiveness.

Analysis 2: The subject device is offered only in a single color (Blue) whereas the predicate is offered in different colors (White/Cobalt Blue/Black/Blue), but the color of the subject device is included by those of the predicate device, so such difference will not bring questions regarding safety and effectiveness.

10.0 Summary of Non-Clinical Performance Testing

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

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

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

ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

ASTM D6978-05(2023) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Table 2: Summary of non-clinical performance testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length: S: ≥220mm M/L/XL: ≥230mm Width: S: 80±10 mm M: 95±10 mm L: 110±10 mm XL: 120±10 mm	Length: S: ≥220mm M/L/XL: ≥230mm Width: S: 84-86/Pass M: 96-102/Pass L: 104-107/Pass XL: 114-116/Pass
		Thickness:	Thickness:

		Palm: ≥0.05 mm Finger: ≥0.05 mm	Finger: 0.09-0.11/Pass Palm: 0.07-0.08/Pass
ASTM D5151 ASTM D6319	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5	0/125/Pass
ASTM D6124 ASTM D6319	Powder Content	Meet the requirement of ASTM D 6124 ≤2.0mg	0.16-0.19mg/Pass
ASTM D412 ASTM D6319	Physical Properties	Tensile Strength: before aging ≥14 Mpa after aging ≥14 Mpa Ultimate Elongation: before aging ≥500 % after aging ≥400 %	Tensile Strength: before aging: 20-24Mpa after aging: 15-23Mpa Ultimate Elongation: before aging: 501-598% after aging: 471-561%
ASTM D6978	Chemotherapy drug claim	The chemotherapy drugs and concentration which have NO breakthrough detected up to 240	The following chemotherapy drugs and concentration had NO breakthrough

		minutes can be suggested for use with the subject device.	detected up to 240 minutes, and can be used with the device. Cyclophosphamide (20.0 mg/ml) Doxorubicin HCl (2.0 mg/ml) Etoposide (20.0 mg/ml) Fluorouracil (50.0 mg/ml) Paclitaxel (6.0 mg/ml) Cisplatin (1.0 mg/ml) Dacarbazine (10.0 mg/ml) The following chemotherapy drugs have low permeation times: Carmustine (3.3 mg/ml): 15 minutes ThioTEPA (10.0 mg/ml): 97 minutes Warning: Not for

			Use with: Carmustine, ThioTEPA
ISO 10993-5	Cytotoxicity	toxicity	Under conditions of the study, device extract is cytotoxic.
ISO 10993-10	Irritation	Non-irritating	Under the conditions of the study, not an irritant. / Pass
ISO 10993-10	Sensitization	Non-sensitizing	Under the conditions of the study, not an sensitizer. / Pass
ISO 10993-11	Acute Systemic Toxicity	Non-acute systemic	Under the conditions of the study, did not show acute systemic toxicity in vivo. / Pass

Table 3 Chemotherapy Permeation Testing Claim

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Cyclophosphamide (20.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Cisplatin (1.0 mg/ml)	>240

Dacarbazine (10.0 mg/ml)	>240
Carmustine (3.3 mg/ml)	15
ThioTEPA (10.0 mg/ml)	97

11.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

12.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device 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 cleared under K220343.