January 4, 2023

RMKH Glove (Cambodia) Co., Ltd.
% Boyle Wang
Official Correspondent
ABMED Service Inc
1312 17th Street
Suite 692
Denver, Colorado 80202

Re: K222907
Trade/Device Name: Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: November 15, 2022
Received: November 15, 2022

Dear Boyle Wang:

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,

Bifeng Qian -S

Bifeng Qian, M.D., 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

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)*
K222907

Device Name
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
The Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustine	3.3 mg/ml	22.6 Minutes
Cisplatin	1.0 mg/ml	240 Minutes
Cyclophosphamide	20.0 mg/ml	240 Minutes
Dacarbazine	10.0 mg/ml	240 Minutes
Doxorubicin HCI	2.0 mg/ml	240 Minutes
Etoposide	20.0 mg/ml	240 Minutes
Fluorouracil	50.0 mg/ml	240 Minutes
Methotrexate	25.0 mg/ml	240 Minutes
Mitomycin C	0.5 mg/ml	240 Minutes
Paclitaxel	6.0 mg/ml	240 Minutes
ThioTepa	10.0 mg/ml	11.0 Minutes
Vincristine Sulfate	1.0 mg/ml	240 Minutes

Please note that the following drugs have low permeation times:
Carmustine 3.3 mg/ml 22.6 Minutes; ThioTepa 10.0 mg/ml 11.0 Minutes.

Tested Fentanyl Citrate is as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection	100.0 mcg/2ml	240 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.

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510(k) Summary

K22907

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

1.0 Submitter's Information

Name: RMKH GLOVE (CAMBODIA) CO., LTD.
Address: Manhattan Special Economic Zone, Bavet Commune, Bavet City, Svay Rieng Province, Cambodia
Contact: Yang Clement KC
Date of Preparation: Dec 28, 2022

Designated Submission Correspondent

Mr. Boyle Wang
ABMED SERVICE INC
Room 1312 17th Street Suite 692 Denver, CO US 80202
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): XS, S, M, L, XL

3.0 Classification

Production code: LZA, LZC, QDO, OPJ
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate Device Information

Manufacturer: Comfort Rubber Gloves Industries Sdn. Bhd
Device: Blue Colored, Power Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
510(k) number: K192954

5.0 Device Description

The subject device is single use, disposable gloves intended for medical purposes to be worn on the examiner's hands to prevent contamination between patient and examiner. The gloves are powder-free, ambidextrous with beaded cuff, blue colored, nitrile, and tested for use with chemotherapy drugs and Fentanyl Citrate. The gloves are offered in five sizes: XS, S, M, L, XL.
The subject device is non-sterile.

6.0 Indication for Use

The Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustine	3.3 mg/ml	22.6
Cisplatin	1.0 mg/ml	＞ 240
Cyclophosphamide	20.0 mg/ml	＞ 240
Dacarbazine	10.0 mg/ml	＞ 240
Doxorubicin HCl	2.0 mg/ml	＞ 240
Etoposide	20.0 mg/ml	＞ 240
Fluorouracil	50.0 mg/ml	＞ 240
Methotrexate	25.0 mg/ml	＞ 240
Mitomycin C	0.5 mg/ml	＞ 240
Paclitaxel	6.0 mg/ml	＞ 240
ThioTepa	10.0 mg/ml	11.0
Vincristine Sulfate	1.0 mg/ml	＞ 240
Fentanyl Citrate Injection	100.0 mcg/2ml	＞ 240

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 22.6 Minutes;
Thio Tepa 10.0 mg/ml 11.0 Minutes.
Warning: Please do not use with Carmustine and ThioTepa.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device (K222907)	Predicate Device (K192954)	Remark
Product Code	LZA,LZC,QDO, OPJ	LZA,LZC,QDO	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	The Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner ' s hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Sterility	Non-Sterile	Non-Sterile	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity,Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Same
Dimensions(mm)	Length: XS/S:≥220; M/L/XL: ≥230;	Length: XS/S/M/L/XL: ≥240; Width:	Similar

		Width: XS: 70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10.		XS:70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10		
Thickness(mm)		Finger: ⩾0.05; Palm: ⩾0.05		Finger: ⩾0.05; Palm: ⩾0.05		Same
Colorant		Blue		Blue		Same
Physical Properties	Before Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min	Same
		Ultimate Elongation	500% min	Ultimate Elongation	500% min	Same
	After Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min	Same
		Ultimate Elongation	400%min	Ultimate Elongation	400%min	Same
Freedom from Holes		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5		Same
Powder Content		0.16~0.30 mg per glove, Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124		Similar
Biocompatibility		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 10993-5 Under conditions of the study, device extract is cytotoxic		ISO 10993-5 Under conditions of the study, device extract is cytotoxic		Same
		ISO 10993-11; Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.		ISO 10993-11; Under the conditions of the study, the subject showed no adverse biological reaction.		Same
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time	Carmustine 3.3 mg/ml	22.6 Minutes		White:18.2 Minutes		Similar
	Cisplatin 1.0 mg/ml	＞240 Minutes		＞240 Minutes		Different
	Cyclophosph	＞240 Minutes		＞240 Minutes		Same

as Tested per ASTM D 6978	-amide 20.0 mg/ml			
	Dacarbazine 10.0 mg/ml	＞240 Minutes	＞240 Minutes	Same
	Doxorubicin HCl 2.0 mg/ml	＞240 Minutes	＞240 Minutes	Same
	Etoposide 20.0 mg/ml	＞240 Minutes	＞240 Minutes	Same
	Fluorouracil 50.0 mg/ml	＞240 Minutes	＞240 Minutes	Same
	Methotrexate 25.0 mg/ml	＞240 Minutes	/	Different
	Mitomycin C 0.5 mg/ml	＞240 Minutes	/	Different
	Paclitaxel 6.0 mg/ml	＞240 Minutes	＞240 Minutes	Same
	ThioTepa 10.0 mg/ml	11.0 Minutes	57.3 Minutes	Different
	Vincristine Sulfate 1.0 mg/ml	＞240 Minutes	/	Different
	Fentanyl Citrate Injection 100mcg/2ml	＞240 Minutes	＞240 Minutes	Same

Analysis 1:
The physical dimensions are different with that of the predicate, but they all meet the requirements of ASTM D6319-19, so the differences do not raise any new safety or performance questions.

Analysis 2:
Powder Content of subject device is similar with that of the predicate, because the predicate did not publish the exact results of the powder content. But they all meet the requirements of ASTM D6319-19, so the differences do not raise any new safety or performance questions.

Analysis 3:
And Breakthrough detection times of Carmustine and Thio Tepa of subject device are different with those of the predicate. The Chemotherapy Labeling Claims has clearly defined on the labeling. So it does not raise any new safety or performance questions.

8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Nitrile Patient Examination Gloves (Tested for Use with Chemotherapy Drugs) was conducted in accordance with the following standards:

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

ISO 10993-5:2009, *Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity*

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

Performance Testing (Bench)

Physical performance qualities of the proposed device were evaluated per ASTM D6319-10, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

Permeation testing was conducted to support the addition of the labeling claim: *Tested for use with chemotherapy drugs*. In addition, the proposed device was tested according to ASTM D6978-05 (Reapproved 2019), *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs.

In summary, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- 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 (Reapproved 2019), *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

Table 2 - Summary of non-clinical performance testing

Test Method	Purpose	Acceptance Criteria			Results
ASTM D6319	Physical Dimensions Test	Length(mm): XS/S: ⩾220; M/L/XL: ⩾230. Width(mm): XS: 70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10.			Length(mm): XS/S: ⩾220; M/L/XL: ⩾230. Width(mm): XS: 78-80/Pass S: 83-86/Pass M: 93-96/ Pass L: 103-106/ Pass XL:113-116/ Pass
		Finger: ⩾0.05; Palm: ⩾0.05			Thickness (mm): Finger: 0.07-0.10/Pass Palm: 0.06-0.07/Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			0/125/Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			0.16-0.30mg/Pass
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	14-29 MPa/Pass
			Ultimate Elongation	≥500%	500-620 %/Pass
		After Aging	Tensile Strength	≥14MPa	14-23 MPa/Pass
			Ultimate Elongation	≥400%	405-589 %/Pass
ISO 10993-5	Cytotoxicity	Non- In Vitro Cytotoxicity			Under conditions of the study, device extract is cytotoxic.
ISO 10993-11	Cytotoxicity	Non- acute systemic toxicity			Under conditions of` the study, did not show acute systemic toxicity in vivo / Pass

ISO 10993-10	Irritation	Non-irritating	Under conditions of the study, not an irritant. / Pass
ISO 10993-10	Sensitization	Non-sensitizing	Under conditions of the study, not a sensitizer. / Pass

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicated device under K192954.