February 13, 2024

W.A. Rubbermate Co., Ltd.
Prachai Kongwaree
President
4 Ramkhamhaeng 19 (Chareonploy)
Huamark
Bangkok, 10240
Thailand

Re: K233740
Trade/Device Name: Black Nitrile Powder Free Patient Examination Glove, Non Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 15, 2023
Received: November 22, 2023

Dear Prachai Kongwaree:

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.

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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233740

Device Name

Black Nitrile Powder Free Patient Examination Glove, Non Sterile

Indications for Use *(Describe)*

A nitrile patient examination glove is a disposable device made of nitrile rubber intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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.

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510k Summary (K233740)

(As Required by 21 CFR 807.92)

1.0 Submitter:

Name	:	Prachai Kongwaree, President, W.A. Rubbermate CO., LTD.
Address	:	**W.A. RUBBERMATE CO., LTD.** 4 Ramkhamhaeng 19 (Chareonploy) Huamark, Bangkok, Thailand 10240
Phone No.	:	66-2-3189442
Date of Summary Prepared	:	13 February 2024

2.0 Identification of the subject device:

Trade Name:	:	Black Nitrile Powder Free Patient Examination Glove, Non Sterile
Common Name:	:	Patient Examination Gloves
Classification Name :	:	Non-powdered patient examination glove
Device Classification	:	I
Regulation Number :	:	21 CFR 880.6250
Product Code	:	LZA

3.0 Predicate Device:

K190942
Trade Name : Disposable Powder Free Nitrile Examination Glove, Black Color
Company: Ever Growth (Vietnam) Co., Ltd

4.0 Description of The Subject Device:

Black Nitrile Powder Free Patient Examination Glove, Non Sterile is manufactured from nitrile rubber. Inner surface of gloves undergoes a surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder or silicone on the glove surface. The glove is ambidextrous, i.e., can be worn on right or left hand.

5.0 Indication for use:

A nitrile patient examination glove is a disposable device made of nitrile rubber intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Comparison of the Technological Characteristics of the Device:

The Black Nitrile Powder Free Patient Examination Gloves, Non Sterile are summarized with the following technological characteristics compared to ASTM D6319 as shown in Table 1

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLACK	BLACK	
510(k) Number	-	K190942	K233740	
Manufacturer(s)	-	Ever Growth (Vietnam) Co., Ltd	W.A. Rubbermate CO., LTD.	Different
Material	ASTM D6319-19	Nitrile	Nitrile	Same
Color	-	Black	Black	Same
Sterility	-	Non-Sterile	Non-Sterile	Same
Handedness	-	Ambidextrous	Ambidextrous	Same
Physical Properties Before Aging Tensile Strength: Ultimate Elongation: After Aging Tensile Strength: Ultimate Elongation:	ASTM D6319-19	 14Mpa, min 500% min 14Mpa, min 400% min	 15.7 – 39.8 Mpa 550 -620% 17.0 – 40.6 Mpa 460- 600%	 Different but within the ASTM standard Different but within the ASTM standard
Length	ASTM D6319-19	230 mm min	Min 240	Different but within the ASTM standard
Thickness: - Finger - Palm	ASTM D6319-19	0.05mm min 0.05mm min	Min 0.13mm for (XS, S, M, L, XL, XXL) Min 0.09mm for (XS, S, M, L, XL, XXL)	Different but within the ASTM standard
Powder Free	ASTM D6124	< 2mg per glove	Below 2mg of residual powder	Similar

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLACK	BLACK	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2021 (E)	Passes	Under the conditions of this study, the test material induced negligible irritation in a rabbit skin single-exposure test.	Same
	Dermal Sensitization- ISO 10993-10: 2010 (E)	Passes	Under the conditions of this study, the frequency of positive challenge results in sample extract and Negative control animals are 0%, the Positive control is 100%, where the test material did not produce a skin sensitization effect in the guinea pigs.	Same
	Cytotoxicity – MEM Elution, ISO 10993-5: 2009	Passes	The study was conducted as the alternative to the cytotoxic test	Different – but an additional test of Acute Systemic Toxicity is conducted and passed
	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Not Tested	Under the conditions of this study, the test item did not induce any acute systemic toxicity reaction in mice.	Different. The subject glove was tested using a systemic toxicity test and passed, but the Predicate did not have the test performed

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLACK	BLACK	
Watertight (1000ml)	ASTM D5151:2019	In accordance with ASTM D6319-10 and ASTM D5151-06 (Reapproved 2011), G-1, AQL 2.5	Tested in accordance with ASTM D5151 (Reapproved 2019) with acceptable results at an AQL 2.5	Similar
Intended use	-	The Nitrile Powder Free Patient examination glove is a non-sterile disposable device intended for medical purpose that is worn on the examiners hands or finger to prevent contamination between patient and examiner.	A nitrile patient examination glove is a disposable device made of nitrile rubber intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Similar
Size	Medical Glove Guidance Manual – Labeling	Extra Small Small Medium Large X Large	Extra Small Small Medium Large Extra Large Extra Extra Large	Similar, with and addition of size Extra Extra Large
Single use	Medical Glove Guidance Manual – Labeling	Single Use	Single Use	Same

7.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical tests for this powder free nitrile examination glove is summarized as per below.

Test Method	Standard	Purpose of Testing	Acceptance Criteria			Results		Status
			[redacted]	Before aging	After aging	Before aging	After aging	
Physical Properties	ASTM D412 (Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension)	To evaluate the tensile (tension) properties of the glove.	Tensile strength	Min 14.0 MPa	Min 14.0 MPa	XS – 22.3 S – 15.7 M – 27.1 L – 24.8 XL – 30.1 XXL – 23.3	XS – 21.2 S – 17.0 M – 30.7 L – 24.2 XL – 23.3 XXL – 23.5	Pass
			Ultimate elongation	Min 500%	Min 400%	XS – 560 S – 540 M – 540 L – 540 XL – 560 XXL – 540	XS – 560 S – 500 M – 500 L – 520 XL – 460 XXL – 520	Pass

Test Method	Standard	Purpose of Testing	Glove Size	Acceptance Criteria		Results		Status
Dimension	ASTM D3767 Standard Practice for Rubber—Measurementof Dimensions	To measure the length, width and thickness ofglove	X-Small	Length	Min 220 mm	Length	240 mm	Pass
				Width	70 ± 10 mm	Width	76.0 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.13 mm 0.10 mm	Pass
			Small	Length	Min 220 mm	Length	241 mm	Pass
				Width	80 ± 10 mm	Width	83.0 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.14 mm 0.10 mm	Pass
			Medium	Length	Min 230 mm	Length	241 mm	Pass
				Width	95 ± 10 mm	Width	95.0 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.13 mm 0.09 mm	Pass
			Large	Length	Min 230 mm	Length	241 mm	Pass
				Width	110 ± 10 mm	Width	105 mm	Pass

				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.13 mm 0.09 mm	Pass
			X-Large	Length	Min 230 mm	Length	240 mm	Pass
				Width	120 ± 10 mm	Width	110 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.14 mm 0.09 mm	Pass
			XX-Large	Length	Min 230 mm	Length	240 mm	Pass
				Width	130 ± 10 mm	Width	121 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.13 mm 0.09 mm	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Watertight	ASTM D5151 (Standard Test Method for Detection of Holesin Medical Gloves)	To detect holes that leak water and thereby compromise the usefulness of the glove.	Sample size: 200 pcs AQL: 2.5, Acceptance No. 10 The batch size for this sampling is 35,001 to 150,000. Hence, according to the single sampling plan GI, the sample to be drawn is under code L equivalent to 200 pieces with accept 10 and reject 11 to be accepted under AQL 2.5	For Size XS, during the test, 1 piece was found with leaks. Hence it falls within the acceptance criteria. For Size S, during the test, 0 piece was found with leaks. Hence it falls within the acceptance criteria. For Size M, during the test, 0 piece was found with leaks. Hence it falls within the acceptance criteria. For Size L, during the test, 1 piece was found with leaks. Hence it falls within the acceptance criteria. For Size XL, during the test, 1 piece was found with leaks. Hence it falls within the acceptance criteria. For Size XXL, during the test, 3 piece was found with leaks. Hence it falls within the acceptance criteria.	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Residual Powder	ASTM D6124 (Standard Test Method for Residual Powder on Medical Gloves)	To determine the amount of residual and non-powder solids found on gloves	Less than 2 mg per glove	Sample size : 5 pcs Result XS :0.26mg/glove Result S :0.50mg/glove Result M :0.16mg/glove Result L :0.52mg/glove Result XL :0.46mg/glove Result XXL :0.48mg/glove	Pass
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2021 (E)	Evaluate the possibility of skin irritation after single topical applications of the test sample extracts on the skin of test subjects.	Observation of skin reaction for erythema and oedema on test subject	Under the conditions of this study, the test material induced negligible irritation in a rabbit skin single-exposure test.	Pass
	Dermal Sensitization ISO 10993-10: 2010 (E)	To evaluate sensitization (maximization test) to evaluate possibility of skin sensitization after topical applications of the test sample extracts on the test subjects	Observation of skin sites for erythema and oedema on test and control test subjects as per Magnusson and Klingman Grading.	Under the conditions of this study, the frequency of positive challenge results in sample extract and Negative control animals are 0%, the Positive control is 100%, where the test material did not produce a skin sensitization effect in the guinea pigs	Pass
	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Evaluate the acute systemic adverse reactions after being injected into test subjects.	No toxicity indication or death in the animal subjected to study.	Under the conditions of this study, the test item did not induce any acute systemic toxicity reaction in mice.	Pass

The following standards were followed to carry out the above testing**:**

- ASTM D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D573 Test Method for Rubber—Deterioration in an Air Oven x ASTM D3578 Specification for Rubber Examination Gloves
- ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151 Test Method for Detection of Holes in Medical Gloves
- ASTM D6124 Test Method for Residual Powder on Medical Gloves
- ISO 2859 Sampling Procedures and Tables for Inspection by Attributes Test results show that under the conditions of the testing, there is no difference inphysical attributes between the proposed device and the predicate device.
- Biocompatibility Testing utilizing: ISO 10993 Biological Evaluation of Medical Devices:
  - ISO 10993 - Part 10: Tests for Irritation and Sensitization. Both Skin Irritation and Dermal Magnuson/Kligman Sensitization performed.
  - ISO 10993 – Part 11: Tests for assessment of Systemic Toxicity

8.0 Summary of Clinical Testing:

No clinical studies are included in this submission.

Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject "Black Nitrile Powder-Free Patient Examination Glove, Non-Sterile" is as safe, as effective, and performs as well as, or better than, the legally marketed predicate device K190942.