July 23, 2022

GoodGloves Industries Sdn Bhd
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K221877
Trade/Device Name: Powder-Free Nitrile 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: June 27, 2022
Received: June 28, 2022

Dear Prithul Bom:

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,

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

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)*
K221877

Device Name
Powder Free Nitrile Examination Glove, Non Sterile

Indications for Use *(Describe)*
The Powder-Free Nitrile Examination Gloves, Non-Sterile (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand 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.

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."

510K SUMMARY – K221877

1.0 Submitter:

Name: Yee Kam Lin
Address: GoodGloves Industries Sdn Bhd
PT 12678, Jalan Techvalley 2, Sendayan Techvalley, Bandar Sri Sendayan, 71950 Seremban, Negeri Sembilan, Malaysia
Phone No.: 06-781 8888

Date of Summary Prepared: July 21, 2022

2.0 Device Description

Common Name	:	Powder-Free Nitrile Examination Gloves
Trade/Proprietary Name	:	Powder Free Nitrile Examination Glove, Non-Sterile
Device Classification	:	Class I
Classification Regulation	:	21 CFR 880.6250 (Non-Powdered Patient Examination Glove)
Product Code	:	LZA (Polymer Patient Examination Glove)

The Powder-Free Nitrile Examination Gloves, Non-Sterile (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The device is for over-the-counter use and single use only.

The Powder-Free Nitrile Examination Gloves, Non-Sterile (Blue) is made of Nitrile, a synthetic rubber copolymer of acrylonitrile and butadiene.

The device does not incorporate powder for purpose other than manufacturing. The final finished glove includes only residual powder from manufacturing. The Powder-Free Nitrile Examination Gloves, Non-Sterile is finishing through polymer coating process.

The device is provided non-sterile.

3.0 Summary of the Technological Characteristics Comparison of the device:

The Powder Free Nitrile Examination Glove, Non-Sterile, meets minimal thickness of 0.06 mm and minimal length of 230 mm respectively.

Non-Clinical Bench Performance Testing Comparison

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
510(k) Number	-	K192333	-	
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN.BHD.	Goodgloves Industries Sdn Bhd	-
Material	ASTM D6319	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Physical Properties <u>Before Aging</u> Tensile Strength: Ultimate Elongation: <u>After Aging</u> Tensile Strength: Ultimate Elongation:	ASTM D6319	Meets 28Mpa min 500% min 30Mpa min 480% min	Meets 14.00 MPa min 500% min 14.00 MPa min 400% min	 Different but within the ASTM standard Different but within the ASTM standard
Thickness : - Finger - Palm - Cuff	ASTM D6319	 0.10mm 0.06mm 0.04mm	 0.05mm min 0.05mm min NA	 Different but within the ASTM standard
Powder Free	ASTM D6124	Less than 2mg per glove	Less than 2mg per glove	Same

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE BLUE	CURRENT BLUE	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010 (E) & Consumer Product Safety Commission Title 16. Chapter II, Part 1500	Non Irritating	All animals were survived and no abnormal signs were observed during the study.	Similar
	Dermal Sensitization- ISO 10993-10: 2010 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	Non Sensitization	No skin sensitization reaction was found in the skin of guinea pig, and the positive rate of sensitization was 0%	Similar
	Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E)	Non Cytotoxic	Findings suggest that the test samples and control sample is not toxic for cell growth.	Similar

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE BLUE	CURRENT BLUE	
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Not Available	There was no evidence of systemic toxicity from the extract	Different
Watertight (1000ml)	ASTM D5151:2019	Inspection Level 1, AQL 1.5	Inspection Level 1, AQL 1.5	Same
Intended 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.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Size	Medical Glove Guidance Manual – Labeling	X Small Small Medium Large Extra Large	Small Medium Large Extra Large	Different
Single use	Medical Glove Guidance Manual – Labeling	Single use	Single use	Same

There are no significant differences between the two products and are identical in terms of intended use, materials design, manufacturing methods except for size, physical properties and thickness. The current device is blue in color and thicker than predicate device.

4.0 Summary of Non-Clinical testing

The performance test data of the non-clinical test for this powder free nitrile examination glove is summarized as 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 glove.	Tensile strength	Min 14.0 MPa	Min 14.0 MPa	14.0 MPa	14.0 MPa	Pass
			Ultimate elongation	Min 500%	Min 400%	Min 500%	Min 400%	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria		Results		Status
Dimension	ASTM D3767 Standard Practice for Rubber— Measurement of Dimensions	To measure the length, width and thickness of glove	Length	Min 230 mm	Length	Min 230 mm	Pass
			Width	Min 95 ± 10 mm	Width	Min 95±10 mm	Pass
			Thickness	Finger – 0.05 mm Palm – 0.05 mm Cuff - NA	Thickness	Finger – 0.05 mm Palm – 0.05 mm Cuff – NA	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 powder and non-powder solids found on gloves.	Less than 2 mg per glove	Sample size : 5 pcs Requirement : <2mg/glove Result : 1.2 mg/glove	Pass
Skin Sensitization	Dermal Sensitization- ISO 10993-10: 2010 (E)	To determine whether the subject device is a sensitizer.	Magnusson and Kligman grades of less than 1	Non- Sensitizer to Guinea Pigs.	Pass
Skin Irritation	Primary Skin Irritation – ISO 10993-10:2010 (E)	To determine whether the subject device is an irritant.	Primary or Cumulative Irritation Index (PII) of 0.4 or less	Non-irritant in New Zealand White Rabbits	Pass
Cytotoxicity	Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E)	To determine whether the subject device is cytotoxic.	Reactivity grade should not be greater than grade 2 or should show "mild reactivity".	Non-Cytotoxic on Hela Cells	Pass

Acute Systemic Toxicity	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	To determine whether the subject device causes a systemic response.	1. No animals showed a significantly greater biological reactivity than animals treated with solvent control. 2.None showed body weight loss > 10%. 3. No mortality or abnormal behavior such as conclusions or prostration occurred in the control group animals.	Does not induce any systemic toxicity in Swiss albino mice	Pass

5.0 Summary of Clinical Summary

Clinical testing is not needed for this device and review.

6.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject Powder Free Nitrile Examination Gloves, Non Sterile, is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K192333.