April 29, 2025

Comfort Rubber Gloves Industries Sdn. Bhd.
Sumathi Saravana Sami
RA Manager
Lot 821
Jalan Matang
Matang, Perak 34750
Malaysia

Re: K250069
Trade/Device Name: Powder Free Natural Rubber Latex Examination Gloves - Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm2 Or Less Protein
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: March 26, 2025
Received: March 26, 2025

Dear Sumathi Saravana Sami:

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,

ALLAN GUAN -S

For 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)*
K250069

Device Name
Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm2 Or Less Protein

Indications for Use *(Describe)*
Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm2 Or Less Protein 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.

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

K250069

Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm^2 Or Less Protein

1.0 Submitter

Name	:	Comfort Rubber Gloves Industries Sdn. Bhd.
Address	:	Lot 821, Jalan Matang, 34750 Matang, Perak Malaysia
Phone No	:	605-847 2777
Fax No	:	605-847 9108
Contact Person	:	Sumathi d/o Saravana Sami (Miss.)
Designation	:	Regulatory Affair Manager
Email	:	s.sumathi@comfortrubber.com
Date of Preparation	:	26th April 2025

2.0 Name of Device

Device Name	:	Powder Free Natural Rubber Latex Examination Gloves – Blue Non-Sterile and Protein Claim Of 50 Micrograms per dm^2 Or Less Protein
Common Name	:	Patient Examination Gloves
Classification Name	:	Patient Examination Gloves (21 CFR 880.6250 product code LYY)
Device Classification	:	Class I
510(K) Number	:	K250069

3.0 Predicate Device

Device Name	:	Blue Latex Examination Powder Free Gloves
Company	:	JR Engineering & medical Technologies (M) sdn. Bhd.
510(K) Number	:	K192329
Device Classification	:	Class I
Product Code	:	LYY

4.0 Description of the Device

Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim of 50 Micrograms per dm^2 or Less Protein are single use. Non sterile, natural rubber latex powder-free examination gloves. They are available in one color (blue) and come in five sizes: Small, Medium, Large, Extra Large, and Extra Extra Large. The subject gloves meet all the requirements of ASTM D3578-19 Standard Specification for Rubber Examination Gloves.

5.0 Indication for Use of the Device

Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm^2 Or Less Protein 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.

6.0 Summary of the Technological Characteristics of the Device

The technological characteristics ofPowder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm^2 Or Less Protein are compared to the predicate device as shown in Table 1.

Table 1: Device General Comparison Table

CHARACTERISTICS	STANDARDS	PREDICATE DEVICE (K192329)	SUBJECT DEVICE	COMPARISON	EXPLANATION
Manufacturer(s)	-	JR Engineering & medical Technologies (M) sdn. Bhd.	Comfort Rubber Gloves Industries Sdn. Bhd	-	-
Product Code	-	LYY	LYY	Same	-
Classification	-	Class I	Class I	Same	-
Regulation Number	-	21 CFR 880.6250	21 CFR 880.6250	Same	-
Name of Device	-	Blue Latex Examination Powder Free Gloves	Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm2 Or Less Protein.	-	-
Indication for Use	-	Blue Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm^2 Or Less Protein 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.	Same	-
Material	ASTM D3578 – 19	Natural Latex	Natural Rubber Latex	Same	-
Color	-	Blue	Blue	Same	-
Surface Appearance	-	Finger Textured	Finger Textured	Same	-

<table>
<tr><th>CHARACTERISTICS</th><th>STANDARDS</th><th>PREDICATE DEVICE (K192329)</th><th>SUBJECT DEVICE</th><th>COMPARISON</th><th>EXPLANATION</th></tr>
<tr><td>Surface Treatment

Powder/Powder Free</td><td>-</td><td>Powder Free</td><td>Powder Free</td><td>Same</td><td>-</td></tr>
<tr><td>Size</td><td>ASTM D3578 – 19</td><td>Small
Medium
Large
Extra Large
Extra Extra Large</td><td>Small
Medium
Large
Extra Large
Extra Extra Large</td><td>Similar</td><td>-</td></tr>
<tr><td>Single use</td><td>Medical Glove Guidance Manual – Labelling</td><td>Single Use</td><td>Single Use</td><td>Same</td><td>-</td></tr>
<tr><td>Sterile/Non-Sterile</td><td>-</td><td>Non-Sterile</td><td>Non-Sterile</td><td>Same</td><td>-</td></tr>
<tr><td>Watertight Test (1000ml)</td><td>21 CFR 800.20

ASTM D5151 – 19</td><td>Pass AQL-2.5</td><td>Pass AQL-2.5</td><td>Same</td><td>-</td></tr>
<tr><td>Dimension - Length</td><td>ASTM D3578 – 19</td><td>Length >230mm
Size | Average
Small | 304
Medium | 304
Large | 305
X-Large | 305
XX-Large | 305</td><td>Length>230mm
Size | Length
Small | 285-290
Medium | 285-294
Large | 286-294
X-Large | 286-290
XX-Large | 296-299</td><td>Similar</td><td>Both the subject and predicate devices meet the same acceptance criteria.</td></tr>
<tr><td>Dimension - Width</td><td>ASTM D3578 – 19</td><td>Width 95±10 mm (for Medium Size)
Size | Average
Small | 84
Medium | 94
Large | 105
X-Large | 114
XX-Large | 123</td><td>Width 95±5 mm (for Medium Size)
Size | Width
Small | 80-81
Medium | 92-93
Large | 103-105
X-Large | 112-114
XX-Large | 123-125</td><td>Similar</td><td>Both the subject and predicate devices meet the same acceptance criteria.</td></tr>
<tr><td>Thickness</td><td>ASTM D3578 – 19</td><td>Palm - >0.08mm
Finger- >0.08mm
Size | Palm (Actual Value) | Finger (Actual Value)
Small | 0.31 | 0.38
Medium | 0.31 | 0.38
Large | 0.31 | 0.38
X-Large | 0.31 | 0.38
XX-Large | 0.31 | 0.38</td><td>Palm - >0.08mm
Finger- >0.08mm
Size | Palm (mm) | Finger (mm)
Small | 0.27-0.29 | 0.33-0.39
Medium | 0.28-0.31 | 0.34-0.40
Large | 0.27-0.29 | 0.35-0.38
X-Large | 0.26-0.28 | 0.36-0.39
XX-Large | 0.26-0.29 | 0.33-0.35</td><td>Similar</td><td>Both the subject and predicate devices meet the same acceptance criteria.</td></tr>
</table>

CHARACTERISTICS	STANDARDS	PREDICATE DEVICE (K192329)		SUBJECT DEVICE		COMPARISON	EXPLANATION
Physical Properties – Tensile Strength	ASTM D3578 – 19	Before Aging Tensile Strength>18MPa		Before Aging Tensile Strength>18MPa		Similar	Both the subject and predicate devices meet the same acceptance criteria.
		Size	Actual Value	Size	Tensile Strength (MPa)		
		Small	33.0	Small	26.20		
		Medium	32.9	Medium	30.04		
		Large	32.2	Large	29.91		
		X-Large	31.9	X-Large	26.15		
		XX-Large	31.1	XX-Large	28.93		
		After Aging Tensile Strength>14MPa		After Aging Tensile Strength>14MPa			
		Size	Actual Value	Size	Tensile Strength (MPa)		
		Small	30.0	Small	26.77		
		Medium	30.6	Medium	24.89		
		Large	29.9	Large	25.71		
		X-Large	29.7	X-Large	23.43		
		XX-Large	28.2	XX-Large	25.86		
Physical Properties – Ultimate Elongation	ASTM D3578 – 19	Before Aging Ultimate Elongation>650%		Before Aging Ultimate Elongation 650% Min		Similar	Both the subject and predicate devices meet the same acceptance criteria.
		Size	Actual Value	Size	Elongation (%)		
		Small	1322	Small	850		
		Medium	1250	Medium	853		
		Large	1392	Large	888		
		X-Large	1130	X-Large	893		
		XX-Large	1149	XX-Large	833		
		After Aging Ultimate Elongation>500%		After Aging Ultimate Elongation>500%			
		Size	Actual Value	Size	Elongation (%)		
		Small	1046	Small	927		
		Medium	1122	Medium	751		
		Large	1257	Large	790		
		X-Large	1011	X-Large	845		
		XX-Large	1110	XX-Large	841		
Powder Residual Content	ASTM D6124-06 (2022)	≤2.0mg/glove		≤2.0mg/glove		Similar	Both the subject and predicate devices meet the same acceptance criteria.
		Size	Residual Powder Content (mg/glove)	Size	Residual Powder Content (mg/glove)		
		Small	0.20	Small	0.24		
		Medium	0.21	Medium	0.38		
		Large	0.22	Large	0.40		
		X-Large	0.22	X-Large	0.54		
		XX-Large	0.23	XX-Large	0.60		

<table>
<tr><th>CHARACTERISTICS</th><th>STANDARDS</th><th colspan="2">PREDICATE DEVICE (K192329)</th><th colspan="2">SUBJECT DEVICE</th><th>COMPARISON</th><th>EXPLANATION</th></tr>
<tr><td rowspan="7">Protein content</td><td rowspan="7">ASTM D5712 – 15 (2020)</td><td colspan="2">Max 200µg/dm^2</td><td colspan="2"><50µg/dm^2</td><td rowspan="7">Similar</td><td rowspan="7">The subject device has a lower acceptance criterion to support a low protein claim.</td></tr>
<tr><td>Size</td><td>Protein Content (µg/$dm^{2)}$</td><td>Size</td><td>Protein Content (µg/$dm^{2)}$</td></tr>
<tr><td>Small</td><td>45</td><td>Small</td><td>43.65</td></tr>
<tr><td>Medium</td><td>44</td><td>Medium</td><td>40.05</td></tr>
<tr><td>Large</td><td>44</td><td>Large</td><td>44.71</td></tr>
<tr><td>X-Large</td><td>43</td><td>X-Large</td><td>42.51</td></tr>
<tr><td>XX-Large</td><td>45</td><td>XX-Large</td><td>48.33</td></tr>
<tr><td rowspan="2">Biocompatibility</td><td><u>Primary Skin Irritation (Predicate Device)</u>

ISO 10993-10:2010(E) /
<u>Animal Irritation Test (Subject Device)</u>

ISO 10993-23:2021

Biological evaluation of medical devices

Part 23: Tests for irritation</td><td colspan="2">Under the conditions of study not an irritant</td><td colspan="2">Under the conditions of the study, not an irritant</td><td>Same</td><td>-</td></tr>
<tr><td><u>Dermal Sensitization Assay</u>

ISO 10993-10:2021

Biological evaluation of medical devices

Part 10: Tests for skin sensitization</td><td colspan="2">Under the conditions of the study, not a sensitizer</td><td colspan="2">Under the condition of this study, not a sensitizer.</td><td>Same</td><td>-</td></tr>
</table>

CHARACTERISTICS	STANDARDS	PREDICATE DEVICE (K192329)	SUBJECT DEVICE	COMPARISON	EXPLANATION
Biocompatibility	In Vitro Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, cytotoxic which is to be expected as latex is the positive control for this test.	Under the conditions of the study, exhibited cytotoxicity reactivity from 100.0% to 6.25% and no cytotoxicity reactivity at 3.125% extract concentrations.	Same	-
	Acute Systemic Toxicity ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	No data provided	Under the condition of this study, the single dose acute systemic toxicity of extracts from test material using both normal saline and cottonseed oil, did not demonstrate any adverse toxic reaction.	Different	Acute systemic toxicity testing was conducted to address the in vitro cytotoxicity
Shelf Life	Medical Glove Guidance Manual	No data provided	3 Years	Different	Does not impact substantial equivalence because the shelf life is determined by specific stability testing conducted under relevant conditions
Type of Use	21 CFR Part 801 Subpart C – Labeling Requirements for Over-the-Counter Devices	Over the Counter (OTC)	Over the Counter (OTC)	Same	-

7.0 Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the length of the gloves	Length: S: >220mm M-XXL:>230mm	Size	Length	
			Small	285-290	
			Medium	285-294	
			Large	286-294	
			X-Large	286-290	
			XX-Large	296-299	
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the width of the gloves	Width: S: 80±10mm M: 95±10mm L: 111±10mm XL: 120±10mm XXL: 130±10mm	Size	Width	
			Small	80-81	
			Medium	92-93	
			Large	103-105	
			X-Large	112-114	
			XX-Large	123-125	
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the thickness of the gloves	Palm - >0.08mm Finger- >0.08mm	Size	Palm (mm)	Finger (mm)
			Small	0.27-0.29	0.33-0.39
			Medium	0.28-0.31	0.34-0.40
			Large	0.27-0.29	0.35-0.38
			X-Large	0.26-0.28	0.36-0.39
			XX-Large	0.26-0.29	0.33-0.35
ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the physical properties – Tensile strength	<u>Before Aging</u> Tensile Strength>18MPa <u>After Aging</u> Tensile Strength>14MPa	Size	Before Aging	After Aging
			Small	26.20	26.77
			Medium	30.04	24.89
			Large	29.91	25.71
			X-Large	26.15	23.43
			XX-Large	28.93	25.86
	To determine the physical properties – Ultimate elongation	<u>Before Aging</u> Ultimate Elongation>650% <u>After Aging</u> Ultimate Elongation >500%	Size	Before Aging	After Aging
			Small	850	927
			Medium	853	751
			Large	888	790
			X-Large	893	845
			XX-Large	833	841
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	S – Pass AQL 2.5 M – Pass AQL 2.5 L – Pass AQL 2.5 XL – Pass AQL 2.5 XXL – Pass AQL 2.5		

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D6124-06(2022) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	≤2.0mg/glove	Size	Residual Powder Content (mg/glove)
			Small	0.24
			Medium	0.38
			Large	0.40
			X-Large	0.54
			XX-Large	0.60
ASTM D5712-15(2020) Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method	To determine the extractable protein in the gloves	<50µg/dm^2	Size	Protein Content (µg/$dm^{2)}$
			Small	43.65
			Medium	40.05
			Large	44.71
			X-Large	42.51
			XX-Large	48.33
ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation	Assessment of medical devices and their constituent materials with regard to their potential to produce irritation	Non-irritating	Under the conditions of the study, not an irritant.	
ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization	Assessment of medical devices and their constituent materials with regard to their potential to induce skin sensitization	Non-sensitizing	Under the condition of this study, not a sensitizer.	
ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	To determine the biological response of mammalian cells in vitro using appropriate biological parameters	Non-cytotoxic	Under the conditions of the study, exhibited cytotoxicity reactivity from 100.0% to 6.25% and no cytotoxicity reactivity at 3.125% extract concentrations	
ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	Evaluation of the potential for medical device materials to cause adverse systemic reactions	No acute systemic toxicity	Under the condition of this study, the single dose acute systemic toxicity of extracts from test material using both normal saline and cottonseed oil, did not demonstrate any adverse toxic reaction.	

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

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

- ASTM D6124-06(2022) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5712-15(2020) Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method
- ASTM D3578-19 Standard Specification for Rubber Examination Gloves
- ISO 2859-1 Sampling Procedures and Tables for Inspection by Attributes
- ISO 10993-5 Biological evaluation of medical devices-Part 5 Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation

8.0 Clinical Performance Data

No clinical study is included in this submission.

9.0 Conclusion

The conclusion drawn from the nonclinical test demonstrate that the proposed device Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm^2 Or Less Protein is as safe, as effective, and performs as well as or better than the legally marketed predicate device, (K192329: Blue Latex Examination Powder Free Gloves).