U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/RPGS
WO66 RMONR
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-2303

Premarket Notification 510(k) Review

Date: March 29, 2022

Reviewer: [redacted]

510(k)# [redacted] **Subject: Traditional**

Applicant: [redacted]

Device Trade Name: Vinyl Co-Polymer Powder-free Examination Gloves, Black

Contact Name: [redacted]

Contact Title: Project Manager

Correspondent Firm: [redacted]

Phone: [redacted] **Email:** [redacted]

Received Date: January 28, 2022

Due Date: April 28, 2022

Pro Code(s): LYZ **Class:** I **Reg #:** 880.6250

Reg Name: Non-Powdered Patient Examination Glove

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
[redacted]	LYZ	Vinyl Co-Polymer Powder Free Examination Gloves	[redacted]

Recommendation

I recommend that the Vinyl Co-Polymer Powder-free Examination Gloves, Black is/are Substantially Equivalent (SESE)

Review Summary

The subject device is a Non-Powdered Patient Examination Glove with the following Indications for Use: "Vinyl Co-Polymer Powder-free Examination Gloves, Black is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner." It is for OTC use.

The performance data and biocompatibility assessment indicate that the subject device is SE to the predicate. Originally, some of the information in the 510k summary and SE comparison were not consistent with the information in the relevant submission sections (e.g. biocompatibility section stated that the device passed cytotoxicity, but the 510k summary and SE comparison said otherwise) and the IFU in the labeling needed editing. The sponsor also needed to identify all materials of the glove by their chemical composition. These issues Were addressed interactively by the sponsor. All outstanding issues have been addressed. The subject device has the same intended use as the predicate. Though the device has different technological characteristics, the methods used to assess the device and its performance are acceptable and the performance data support that the device is substantially equivalent to the proposed predicate. Therefore, I recommend that the subject device is substantially equivalent to the proposed predicate device.

Review Team

Lead Reviewer [redacted]

I. Purpose and History

TPLC Information Recall Information Historyfalls

The subject 510(k) was received on 1/28/22 and accepted for review on 2/10/22. The purpose of the submission is to seek clearance for a black vinyl exam glove.

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Statement

The content of the 510(k) Summary is complete. Some of the information for the predicate device was not consistent with the publicly available information for the predicate and the summary originally stated that the subject device failed cytotoxicity, which was not accurate. This issue was addressed interactively.

Reviewer Recommendation

The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Is there a new intended use, or different technology that raises different questions of S&E?	Undo	No

Device Description Information	Red = Inadequate or Unanswered	Yellow = Marked
Device is life-supporting or sustaining: No		
There are direct/indirect tissue contacting components: Yes		
• **Device or a component is an implant:** No		
Device uses software/firmware: No		
Device or component packaged as sterile: No		
Use/Reuse information: SUD (Packaged Sterile/Not Sterile)		
Environments of Use: Professional Healthcare Facility, Home		
Combination Product Type: N - Not a Part 3 Combination Product		
The Device/System is electrical: No, the device is not electrical		
Device Attributes		
Nanotechnology present: No		
Reprocessed SUD: No		
Medical Counter Measures: No		
Animal-Derived Material(s): No		

The device is a black, vinyl co-polymer exam glove. The device is proposed to come in 5 sizes: XS, S, M, L, XL. The sponsor provided dimensional information for the different sizes:

Technological Characteristics	Standard/Test/FDA Guidance	Inspection Level and AQL	Result Summary	Conclusion
Overall Length (mm)	230mm for all sizes, min	[redacted]		Pass
Width (mm)	XS:75±5			Pass
	S: 85±5			
	M: 95±5			
	L: 105±5			
	XL: 115±5			
Palm Thickness (mm)	0.08mm minimum			Pass
Finger Thickness (mm)	0.08mm minimum			Pass

The sponsor provided the following information regarding the device materials:

#	Chemical Name	Function
001	PVC	Main Raw Material Used
002	Plasticizer	Plasticizer
003	[redacted]	Main Raw Material Used
004		Stabilizer
005	TXIB	Plasticizer and Viscosity Reducing Agent
006	Pigment	Pigment
007	PU	Surface Treating Agent

The glove is identified as "vinyl co-polymer" and the sponsor specifies that the device is [redacted] plasticizer with the remaining mass percentage made up of the other manufacturing compounds.

The sponsor originally did not identify the plasticizer, TXIB, pigment, or PU materials that comprise the final finished device. This issue was resolved interactively. The sponsor provided MSDSs for these materials that identified the compounds used:

Pigment: Carbon black – CAS: 1333-86-4
Plasticizer: Bis(2-ethylhexyl) terephthalate – CAS: 6422-86-2
PU: Polyurethane resin (in a water emulsion) – CAS: 71394-21-3
TXIB: 2,2,4-trimethyl-1,3-pentanediol diisobutyrate – CAS: 6846-50-0

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Reviewer Recommendation
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use	
Subject	
510(k) #: [redacted]	Rx/OTC: OTC

Comparison of Indications for Use								
Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☒	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use: Vinyl Co-Polymer Powder-free Examination Gloves, Black is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Predicate(s)

Submission#: [redacted] Rx/OTC: OTC

Intended Population: Adults

Indications for Use: A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Reviewer Recommendation

The Comparison of the Indications for Use is acceptable.

V. Comparison of Technology to Predicate Devices

#	Proposed Device	Predicate Device [redacted]	Remark
Trade Name	Vinyl Co-Polymer Powder-free Examination Gloves, Black	Vinyl Co-Polymer Powder-free Examination Gloves, Blue color	Similar
Product Code	LYZ	LYZ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	Subject device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Materials	vinyl and oil-based liquid nitrile rubber	vinyl and oil-based liquid nitrile rubber	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Black	Blue	Different
Single use	Single use	Single use	Same
Length	Minimum 230mm	Minimum 230mm	Same
Palm Width (size) (mm)			
XS	75±5	75±5	Same
S	85±5	85±5	Same
M	95±5	95±5	Same
L	105±5	105±5	Same
XL	115±5	115±5	Same
Thickness(mm)			
Finger	Minimum 0.08	Minimum 0.08	Same
Palm	Minimum 0.08	Minimum 0.08	Same
Tensile Strength, Before Aging	11MPa, min	11MPa, min	Same
Ultimate Elongation, Before Aging	300%, min	300%, min	Same
Tensile Strength, After Accelerated Aging	11MPa, min	11MPa, min	Same
Ultimate Elongation, After Accelerated Aging	300%, min	300%, min	Same
Freedom from holes	In accordance with ASTM D 5151-19, following ASTM D5250- 19, G-I, AQL 2.5	In accordance with ASTM D 5151-19, following ASTM D5250-19, G-I, AQL 2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	Same

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	**Yes**	Undo
Usability Consult Needed?	Yes	No

Labeling Information	**Red = Inadequate or Unanswered**	**Yellow = Marked**

Prescription statement included: Inapplicable

Adequate OTC instructions: Yes

Indications for Use consistent with IFU page: Yes

Appropriate Contraindications, Warnings, Precautions & Adverse Events: Yes

Instructions in accordance with guidance: Yes

Appropriate labeling inside device: Inapplicable

Appropriate labeling outside device: Inapplicable

Appropriate instructions for use labeling: Yes

Appropriate Home Use information: Yes

MR Status according to labeling: Not Evaluated and Not Needed

The sponsor provided draft labeling that includes the device name, "powder free", "single use", number of devices by count, manufacture's or distributor's address, country of origin, and lot number. It does not include information indicating a shelf life.

The sponsor was interactively requested to provide revised labeling to ensure that the IFU in the labeling is identical to the IFU in the IFU form. Revised labeling was provided as requested.

Outer case: **(TOP AND SIDE)**

Vinyl Co-Polymer Examination Gloves

Powder Free
Non-Sterile
Single use only
Ambidextrous

Black

Contents: 100 each per box
1,000 each per case

Size: XS, S, M, L, XL

Manufactured by: [redacted]

Or
Distributed by: (Many Distributors)

Lot Number: 000000

MADE IN CHINA

Inner Box: **(TOP AND SIDE):**

Vinyl Co-Polymer Examination Gloves

Powder Free
Non-Sterile
Single use only
Ambidextrous

Black

Contents: 100 Gloves by Count

Size: XS, S, M, L, XL

MADE IN CHINA

(BOTTOM OF THE BOX)

Vinyl Co-Polymer Powder-free Examination Gloves, Black is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Caution & Storage conditions: Keep dry. Shield from direct sunlight, fluorescent lighting, x-rays.

:

Manufactured by: [redacted]

or

Distributed by: (Many Distributors) Lot Number: 000000

MADE IN CHINA

Reviewer Recommendation

The Labeling is acceptable. The IFU in the labeling was revised to be identical to the IFU in the IFU form.

VII. Reprocessing, Sterility and Shelf-Life

The device is non-sterile and no shelf life is claimed. This is acceptable for an exam glove.

Reviewer Recommendation

Reprocessing, Sterility and Shelf-Life information is acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	**Yes**	Undo
Biocompatibility Consult Needed?	Undo	**No**

Biocompatibility Information	**Red = Inadequate or Unanswered**	**Yellow = Focal Point**	
There is/are 1 tissue contacting products/components/materials.			
Material compositions described?: Yes			
Device has Special Considerations?: No			
Table of Materials and Rationales			
Component	**Material**	**Type of Contact**	**Identical Material & Rationale**
Black vinyl glove	PVC, nitrile, colorant	Direct	No, No Rationale
Rationale			
Rationale: No rationale provided.			
Biocompatibility Material 1:			

Biocompatibility Information **Red** = Inadequate or Unanswered **Yellow** = Focal Point

Test Component/Material: Black vinyl glove / PVC, nitrile, colorant

Potential for Repeat Exposure?: Yes

Type of Tissue Contact: Surface Device: Skin

Duration of Contact: [redacted] hours

Cytotoxicity Testing **Red** = Inadequate or Unanswered **Yellow** = Focal Point

Cytotoxicity testing conducted: Another method

Comments: The sponsor used a quantitative MTT assay per ISO 10993-5. The test article, controls, extraction methods, and experimental methods used were acceptable. The study indicated no cytotoxic potential. The cell viability of the 100% test article was 91.9%.

Sensitization Testing **Red** = Inadequate or Unanswered **Yellow** = Focal Point

Sensitization testing conducted: Yes, [redacted]

Test Article: Black vinyl co-polymer exam glove

Extraction Conditions	Methods	Results	Conclusion and Recommendation
[redacted]		**Normal & No Deaths?:** Normal appearance, no deaths **Polar extract score < 1.0?:** Yes, Test and Control < 1.0 **Non-Polar extract score < 1.0?:** Yes, Test and Control < 1.0 **Positive Control ≥ 1.0?:** Yes	**Sensitizing Potential:** Non-Sensitizer **Recommendation:** Acceptable

Comments:

Irritation Testing **Red** = Inadequate or Unanswered **Yellow** = Focal Point

Irritation testing conducted: Yes, Dermal Irritation Test

Test Article: black vinyl co-polymer glove

Sample Prep / Extract Conditions	Methods	Results	Conclusion and Recommendation
[redacted]		**Proper Procedure?:** Yes **Normal & No Deaths?:** Normal appearance, no deaths	**Irritant Potential:** 0-0.4 negligible irritant **Recommendation:** Acceptable

Biocompatibility Information	Red = Inadequate or Unanswered	Yellow = Focal Point
[redacted]	**Polar Index:** ≤ 0.4 **Non-Polar Index:** ≤ 0.4	
Comments:		

The sponsor also conducted acute systemic toxicity testing of the exam gloves using male mice as the test system. The methods used are consistent with ISO 10993-11. The gloves were extracted in 0.9 % Sodium Chloride Injection and Sesame Oil for 72 hours at 50 °C at a ratio of 6 cm^2: 1 ml. The polar extract group mice were administered by intravenous injection (n=5 for each glove). The non-polar extract group mice were administered by intraperitoneal injection (n=5 for each glove). The control groups were administered saline or Sesame Oil (n=5 for each extraction vehicle for each glove). The injection dosage was 50 mL/kg. The mice were weighted every day during the study. Clinical signs were monitored immediately after injection and at 4, 24, 48, and 72 hours. All animals survived the study and no abnormal clinical signs were observed. All animals gained weight during the study period. The results of the acute systemic toxicity studies indicate that the device extracts did not induce an acute, systemic toxic response. These results are acceptable.

Reviewer Recommendation

The Biocompatibility information is acceptable.

IX. Software/Firmware & Cybersecurity/Interoperability

Reviewer Recommendation

N/A

X. EMC, Wireless, Electrical, Mechanical and Thermal Safety & Risk Analysis

Reviewer Recommendation

N/A

XI. Performance Testing

A Bench Testing

The sponsor provided a declaration of conformity declaring complete conformance to ASTM D5250-19, Standard Specification for Poly (vinyl chloride) Gloves for Medical Application, and ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves. They claim conformance to Section 6, Procedure I of ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves, which include the methods for quantification of powder on powder-free gloves.

The sponsor provided dimensional testing (length, width, thickness; n=13), tensile strength and elongation before and after aging (n=13), water leak testing (n=125), and residual powder testing (n=5) for each glove size (XS, S, M, L, XL).

Summary Table of performance testing

Technological Characteristics	Standard/Test/FDA Guidance	Inspection Level and AQL	Result Summary	Conclusion
Overall Length (mm)	[redacted]			Pass
Width (mm)				Pass
Palm Thickness (mm)				Pass
Finger Thickness (mm)				Pass
Tensile Strength (Mpa)				
Before aging				Pass
After aging				Pass
Ultimate Elongation (%)				
Before aging				Pass
After aging				Pass
Pinhole				Pass
Residual Powder				Pass

All [redacted] samples passed dimensional testing and tensile strength/elongation testing (before and after aging) for each size. For water leak testing, all [redacted] samples passed for the XS, S, and M sizes and [redacted] samples passed for the L and XL and sizes. All sizes passed the residual powder content testing:

Size	XS	S	M	L	XL
Sample quantity	5	5	5	5	5
Powder residue (mg/glove)	0.35	0.42	0.48	0.54	0.68
Powder Content Criteria: Not more than 2mg/glove for powder free glove.					

B Animal Testing

C Clinical Testing

Is one or more of the prior clinical investigations subject to requirements governing FDA acceptance of data from clinical investigations?	Yes No

Reviewer Recommendation

The Performance Testing [Verification & Validation] is acceptable.

XII. Summary of Benefit-Risk and Signal Assessment

In comparison to the predicate device, has the review team or the sponsor identified one of the following scenarios for the subject device: 1) An increase in risk AND an increase or equivalent benefit; OR 2) A decrease in benefit AND a decrease or equivalent risk?	Undo **No**

XIII. Kit Certification

N/A

XIV. References

XV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
1. Is the predicate device legally marketed?	☒	☐
2. Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: Both devices are intended to be worn on the hand as barrier PPE.		
3. Do the devices have the same technological characteristics?	☐	☒
Please describe the different technological characteristics: Different colorants, different physical properties		
4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	☐	☒
5a. Are the methods acceptable?	☒	☐
5b. Do the data demonstrate equivalence and support the Indications for Use?	☒	☐
Please explain how the data do or do not demonstrate substantial equivalence: The subject devices meets the standard performance specifications for a vinyl exam glove.		

XVI. Original Major Deficiencies

XVII. Original Minor Deficiencies

XVIII. Original Additional Considerations

XIX. Contact History

3/23/22 – Lead reviewer sent interactive information request to sponsor.
3/24/22 – Sponsor provided interactive additional information.

Digital Signature Concurrence Table (Doc ID: 04500.14.06)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off	[redacted] Digitally signed by [redacted] S Date: 2022.03.29 16:35:07 -04'00'