510(k) Summary
K182117

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

1.0 submitter's information

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2.0 Device information

Trade name: Vinyl Patient Examination Gloves

Common name: Vinyl Patient Examination Gloves (Powder Free)

Regulation name: Non-Powdered Patient Examination Glove

Model(s): XS, S, M, L, XL

3.0 Classification

Production code: LYZ
Regulation number: 21 CFR 880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate device information

Manufacturer: Hebei Hongtai Plastic Products Company Limited

Device: Vinyl Patient Examination Gloves (White, Blue, Yellow)
510(k) number: K163168

5.0 Intended use

The Vinyl Patient Examination Glove is a disposable device intended for medical purposes that is worn on the examiners hands to prevent contamination between patient and examiner.

The intended use and the indication for use of Vinyl Patient Examination Glove, as described in its labeling are the same as the predicate device Vinyl Patient Examination Gloves (White, Blue, Yellow) (K163168).

6.0 Device description

The proposed device is Powder Free Vinyl Patient Examination Gloves. The proposed device is clear, non-colored. The design of proposed device is addressing the standards as ASTM D6124, ASTMD5151, and ASTMD5250. The proposed device is non-sterile.

7.0 Technological Characteristics Comparison Table

Table1-General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	LYZ	LYZ	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Indications for Use	The Vinyl Patient Examination Glove is a disposable device intended for medical purposes that is worn on the examiner’s hands to prevent contamination between patient and examiner.	The Vinyl Examination Glove (White, Blue, or Yellow) is a disposable device intended for medical purposes that is worn on the examiner’s hands to prevent contamination between patient and examiner.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous	ambidextrous	Same
Surface Feature	Smooth	Smooth	Same
Labeling Information	Single-use indication,	Single-use indication,	Same

	powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	

Table2 Device Dimensions Comparison

Predicate Device(K163168)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	235	245	245	min
	Width, mm	80	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.08					min
Proposed Device	Designation	Size					Tolerance
		XS	S	M	XS	S	
	Length, mm	230	230	235	245	245	min
	Width, mm	80	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.08					min
Remark	SAME						

Table3 Performance Comparison

Item			Proposed device	Predicated device	Remark
Colorant			Clear, Non-Colored	White, Blue, Yellow	Analysis1
Physical Properties	Before Aging	Tensile Strength	15MPa, min	15MPa, min	SAME
		Ultimate Elongation	380%min	380%min	SAME
	After Aging	Tensile Strength	15MPa, min	15MPa, min	SAME
		Ultimate Elongation	380%min	380%min	SAME
	Comply with ASTM D5250			Comply with ASTM D5250	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTMD5151 AQL=1.5	Be free from holes when tested in accordance with ASTMD5151 AQL=1.5	SAME
Powder Content			0.48	Meet the requirements of ASTM D6124	SIMILAR

Analysis1：The proposed device has a different color in comparison to the predicate device. The difference in color of the subject device did not raise a safety concern because biocompatibility test results were passing for the subject device.

Table4 Safety Comparison

Item		Proposed device	Predicated device	Remark
Material		Vinyl	Vinyl	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO10993-10	SAME
	Sensitization	Under conditions of the study, not a sensitizer.		
	Cytotoxicity	Under conditions of the study, not cytotoxic	/	SIMILAR
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

8.0 Discussion of non-clinical and clinical test performed

Non-clinical tests were conducted on the proposed subject device to demonstrate that the device met all design specifications. The test results demonstrated that the proposed device complies 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

ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves

ASTMD5151-06(Reapproved2015), Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D5250-06 (Reapproved 2015), Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.

Clinical testing is not needed for this device.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicated device.