510(K) Summary

"The assigned 510(k) number is: K173017"

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name:	Anhui Kindguard Medical Supplies Technology Co.,Ltd
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Date of preparation:	2017-09-16

2.0 Name of th e Device

Device Name:	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Proprietary/Trade name:	Kindguard Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
CommonNam e	Exam gloves
Classification Name:	Patient examination glove
Device Class ification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Product Code:	LYZ

3.0 Predicate device

Device Name:	Powder-Free Vinyl Patient Examination Glove (Non-colored)
Company name:	Zhang Jia Gang Fengyuan Plastic Product Co. Ltd.
510(K) Number:	K091663.

4.0 Device Description:

4.1 How the device functions:

PVC films form a barrier to prevent contamination between patient and examiner

4.2 Scientific concepts that form the basis for the device

The PVC rubber is water tight under normal conditions of use. Its tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

4.3 Physical and performance characteristics such as design, materials and physical properties:

The Poly (vinyl chloride) glove acts as a barrier to prevent contamination between patient and examiner. The glove is manufactured in accordance with the requirements of ASTM D5250 and ASTM D5151.

5.0 Device Intended Use (Indication for use):

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard		
Dimension	ASTM D 5250-06(Reapproved 2011).		
	Length	≥230mm	
	Width	Small	80-90 mm
		Medium	90-100mm
		Large	100-110mm
		X large	110-120 mm
	Thickness	Fingertip	≥0.05mm
		Palm	≥0.08mm
Physical Properties	ASTM D 5250-06(Reapproved 2011).		
	Tensile strength (Before & After aging)		≥11MPa
	Elongated rate (Before & After aging)		≥300%
Freedom from pinholes	• 21 CFR 800.20 • ASTM D5250-06(Reapproved 2011) • ASTM D5151-06(Reapproved 2011)		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D 5250-06 (Reapproved 2011).and D6124-06(Reaffirmation 2011)		Meets <2mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: 2010-08-01		Passes Under the conditions of the study, the subject device is not a primary skin irritant.
	Dermal sensitization in the guinea pig ISO 10993-10: 2010-08-01		Passes Under the conditions of the study, the subject device is not a skin sensitizer.

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data:

Kindguard Powder Free Vinyl Patient Examination Gloves, Clear (non-colored), meet requirements per ASTM D5250-06 (Reapproved 2011), per ASTM D6124-06 Reaffirmation 2011), per 21 CFR 800.20 and ISO 10993-10:2010-08-01.

The performance test data of the nonclinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data was not needed to demonstrate that the subject glove is substantially equivalent to the predicate glove. Determination of substantial equivalence is not based on an assessment of clinical performance data.

9.0 Substantial Equivalence Comparison:

Features & Description			Predicate Device	Subject Device	Result of Comparison
Company			Zhang Jia Gang Fengyuan Plastic Product Co.Ltd.	Anhui Kindguard Medical Supplies Technology Co.,Ltd	--
510(K) Number			K091663		--
Product name			Powder Free Vinyl Patient Examination Gloves, Clear (Non-colored)	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)	Same
Product Code			LYZ	LYZ	Same
Size			Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	Same
Intend for use			Powder free Vinyl Patient Examination Gloves, Clear(Non-colored)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.	Powder free Vinyl Patient Examination Gloves, Clear (Non-colored) 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
Device Description and Specifications			Meets ASTM D5250-06	Meets ASTM D5250-06 (Reapproved 2011)	Same
Dimensions Length (mm) IL S-2 AQL4.0	≥230mm		231-241mm	232-241mm	Same
Dimensions Width (mm) IL S-2 AQL4.0	Small	80-90	81-89	82-88	Same
	Medium	90-100	93-99	93-98	
	Large	100-110	102-110	102-108	
	X large	110-120	111-1119	113-118	
Dimensions Thickness (mm) IL S-2 AQL4.0	Finger	≥0.05	0.05-0.10	0.08-0.11	Same
	Palm	≥0.08	0.09-0.13	0.10-0.12	
Physical Properties IL S-2 AQL4.0	Before aging/after aging				Same
	Elongation ≥300%		340-410%	350-420%	
	Tensile Strength ≥ 14MPa		15-25 MPa	15-20 MPa	

Freedom from Pinholes	Holes at Inspection Level I AQL2.5	Holes at Inspection Level I AQL2.5	Holes at Inspection Level I AQL2.5	Same
Residual Powder	below 2mg of residual powder	0.3mg	0.1mg	Same
Materials used to fabricate the devices		PVC	PVC	Same
Dusting or Donning Powder: name		Surface Coating Agent	Surface Coating Agent	Same
Compare performance data supporting substantial equivalence		Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Same
Single Patient Use		Single Patient Use	Single Patient Use	Same
Biocompatibility		Under the conditions of this study, not an irritant and Under the conditions of this study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1 :2006	Under the conditions of this study, not an irritant and Under the conditions of this study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10 Third Edition 2010-08-01	Same
Labeling for the legally marketed device to which substantial equivalence is claimed.		-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot	Same

10.0 Substantial Equivalence Comparison:

Discussion: The Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) meet the ASTM standard or equivalent standard and FDA requirements for water leak test on pinhole AQL., meeting labeling claims.

The subject device The Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) has the same intended use and technological and performance characteristics as the predicate device Powder-Free Vinyl Patient Examination Glove (Non-colored) Zhang Jia Gang Plastic Product Co., Ltd. K091663, and therefore the devices are substantially equivalent.

Conclusion: The Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is as safe, as effective, and performs as well as the predicate device, Powder-Free Vinyl Patient Examination Glove (Non-colored) Zhang Jia Gang Plastic Product Co., Ltd. K091663.