



November 15, 2017

Anhui Kindguard Medical Supplies Technology Co.,Ltd
% Chu Xiaohan
Official Correspondent
Beijing Easylink CO.,LTD
Rm. F302 Bldg., 41, Jing Cheng Ya Ju
Courtyard 6 of Southern Dou Ge Zhuang
Beijing, 100121 Cn

Re: K173016

Trade/Device Name: Kindguard Powder Free Vinyl Patient Examination Gloves, Light Yellow Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: September 15, 2017
Received: September 27, 2017

Dear Chu Xiaohan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -S

for

Tina Kiang, PhD

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173016

Device Name

Kindguard Powder Free Vinyl Patient Examination Gloves, Light Yellow Color

Indications for Use (Describe)

Kindguard Powder Free Vinyl Patient Examination Gloves, Light Yellow Color 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.

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

"The assigned 510(k) number is: K173016 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name : Anhui Kindguard Medical Supplies
Technology Co.,Ltd
Submitter's address : Intersection of Yulan Road and Chaoyang
Road, Sixian County, Suzhou City,
Anhui, 234300, China
Phone number : 0086-557-7606789
Fax number : 0086-557-7606789
Name of contact person: Chen wei
Date of preparation : 2017-11-14

2.0 Name of the Device

Device Name: Powder Free Vinyl Patient Examination
Gloves, Light Yellow Color
Proprietary/Trade name: Kindguard Powder Free Vinyl Patient
Examination Gloves, Light Yellow Color
Common Name: Exam gloves
Classification Name: Patient examination glove
Device Classification: I
Regulation Number: 21 CFR 880.6250
Panel: General Hospital
Product Code: LYZ

3.0 Predicate device

Device Name: Powder Free Vinyl Patient Examination Gloves,
Light Yellow Color
Company name: Jiangsu Healthcare Products Co., Ltd.
510(K) Number: K131831

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, Light Yellow Color 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, Light Yellow Color 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, Light Yellow Color, 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. So 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			Jiangsu Healthcare Products Co., Ltd.	Anhui Kindguard Medical Supplies Technology Co.,Ltd	--
510(K) Number			K131831	K173016	--
Product name			Powder Free Vinyl Patient Examination Gloves, Light Yellow Color	Powder Free Vinyl Patient Examination Gloves, Light Yellow Color	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, Light Yellow Color 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, Light Yellow Color 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) ILS-2 AQL4.0	$\geq 230\text{mm}$		231-241mm	232-243mm	Similar
Dimensions Width (mm) IL S-2 AQL4.0	Small	80-90	81-89	83-87	Similar
	Medium	90-100	93-99	94-96	
	Large	100-110	102-110	103-107	
	X large	110-120	111-1119	114-119	
Dimensions Thickness (mm) IL S-2 AQL4.0	Finger	≥ 0.05	0.05-0.10	0.08-0.11	Similar
	Palm	≥ 0.08	0.09-0.13	0.10-0.11	
Physical Properties IL S-2 AQL4.0	Before aging/after aging				Same
	Elongation $\geq 300\%$		340-410%	350-410%	
	Tensile Strength $\geq 14\text{MPa}$		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	Similar
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, Light Yellow Color meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meeting labeling claims.

The subject device Powder Free Vinyl Patient Examination Gloves, Light Yellow Color has the same intended use and technological and performance characteristics as the predicate device Powder Free Vinyl Patient Examination Gloves, Light Yellow Color Jiangsu Healthcare Products Co., Ltd. K131831.

Conclusion: Based on the nonclinical tests data, it can be concluded that the Powder Free Vinyl Patient Examination Gloves, Light Yellow Color is as safe, as effective, and performs as well as the predicate device, Powder Free Vinyl Patient Examination Gloves, Light Yellow Color Jiangsu Healthcare Products Co., Ltd. K131831.