



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 16, 2015

Anhui Anyu Latex Products Co., Ltd.
c/o Doris Dong
Shanghai CV Technology Co., Ltd.
Room 1706, No. 128 Songle Rd., Songjiang Area
Shanghai 201600
CHINA

Re: K150612

Trade/Device Name: “Annuy Latex Patient Examination Glove (Powdered and Powder-free)” &
“Annuy Nitrile Patient Examination Glove (Powdered and Powder-free)”

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient examination glove

Regulatory Class: Class I

Product Code: LYY, LYZ

Dated: October 4, 2015

Received: October 16, 2015

Dear Ms. Dong:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)

K150612

Device Name

Annuy Latex Patient Examination Glove (powdered and powder-free);
Annuy Nitrile Patient Examination Glove (powdered and powder-free)

Indications for Use (Describe)

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Section 5

510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number: K150612
Date: Sept 30th, 2015
Type of 510(k) Submission: Traditional
Basis for 510(k) Submission: New device
Submitter/Manufacturer: Anhui Anyu Latex Products Co., Ltd
East Qinji Road & North Xinghua Road, Bengbu, Anhui, 233010 China
Contactor: Doris Dong (Consultant)
Shanghai CV Technology Co., Ltd.
Room 1706, No. 128 Songle Rd., Songjiang Area, Shanghai, 201600 China
E-mail: doris_d@126.com
Tel: 86 21-31261348 / Fax: 86 21-37824346

2. Device Description:

Proprietary Name: Anny Latex Patient Examination Glove (powdered and powder-free);
Anny Nitrile Patient Examination Glove (powdered and powder-free)

Common Name: Latex Examination Gloves (powdered and powder free);
Nitrile Examination Gloves (powdered and powder free)

Classification Name: Glove, patient examination, latex;
Glove, patient examination, poly

Product Code: LYY & LZA

Device Class: I

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

Indications for use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

Device Description: Anny Latex Patient Examination Glove (powdered and powder-free) is a glove made from natural rubber that covers the hand up to the wrist. It is cuffed and equally wearable on either hand, free from differentiation between the left hand and the right. It has three sizes, i.e., large, medium, and small. All variations share the same natural color, creamy white. The glove is non-sterile and is for single use only, to be discarded after each examination is performed. It acts as a barrier between the examiner and the subject being examined in order to prevent contamination between them.

Anny Nitrile Patient Examination Glove (powdered and powder-free) is a glove made from nitrile butadiene rubber Latex that covers the hand up to the wrist. It is cuffed and equally wearable on either hand, free from differentiation between the left hand and the right. It has three sizes, i.e. large, medium, and small. All variations share the same blue color. The glove is non-sterile and is for single use only, to be discarded after each examination is performed. It acts as a barrier between the examiner and the subject being examined in order to prevent contamination between them.



3. Predicate Device Identification

510(k) Number: K072145

Product Name:

Latex Examination Gloves (Powdered and Powder-Free)

Nitrile Examination Gloves (Powdered and Powder-Free)

Manufacturer: Zhanjiang Jiali Glove Products Co., LTD

4. Performance Test Data Summary

• **The Powdered Latex Patient Examination Gloves**

Characteristics	Standard		Test Data	
Dimension	ASTM D3578-10			
Palm width	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	80±10	80~84	
	Medium	95±10	93~97	
	Large	111±10	107~109	
Overall Length	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	220 min	240~246	
	Medium	230 min	241~248	
	Large	230 min	240~249	
Finger Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.08 min	0.09~0.11	
	Medium	0.08 min	0.09~0.11	
	Large	0.08 min	0.09~0.12	
Palm Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.08 min	0.10~0.12	
	Medium	0.08 min	0.10~0.12	
	Large	0.08 min	0.09~0.12	
Physical Properties				
	ASTM D3578-10			
	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>
- Tensile Strength	18Mpa min	14Mpa min	20.3~35.1Mpa	16.7~24.0Mpa
- Ultimate Elongation	650% min	500% min	961~1233%	748~1021%
- Stress at 500% Elongation	5.5Mpa max	--	4.6~5.4Mpa	--
Freedom from Holes	ASTM D5151-11		Passed Standard Acceptance Criteria Holes at Inspection Level I, AQL 2.5	
Powder Amount	ASTM D6124-11, ≦ 10mg/dm ²		2.34 mg/dm ² , Meets ASTM D6124-11 Results generated values below 10mg/dm ² of residual powder	
Protein Content	ASTM D5712-10, ≦ 200µg/dm ² Aqueous extractable protein		Aqueous extractable protein: 72.1 mcg /dm ² , Meets ASTM D5712-10, Results generated values below 200µg/dm ² of aqueous extractable	



		protein content
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10:2010-08-01	Under the condition of the test, not an irritant.
	Dermal sensitization in the guinea pig ISO 10993-10:2010-08-01	Under the condition of the test, not a sensitizer.

● The Powder-free Latex Patient Examination Gloves

Characteristics	Standard		Test Data	
Dimension	ASTM D3578-10			
Palm width	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	80±10	80~84	
	Medium	95±10	93~97	
	Large	111±10	107~109	
Overall Length	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	220 min	240~246	
	Medium	230 min	241~248	
	Large	230 min	241~248	
Finger Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.08 min	0.09~0.12	
	Medium	0.08 min	0.09~0.11	
	Large	0.08 min	0.09~0.12	
Palm Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.08 min	0.10~0.12	
	Medium	0.08 min	0.10~0.12	
	Large	0.08 min	0.08~0.12	
Physical Properties	ASTM D3578-10			
	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>
- Tensile Strength	18Mpa min	14Mpa min	18.4~32.3Mpa	18.7~24.5Mpa
- Ultimate Elongation	650% min	500% min	955~1148%	797~976%
- Stress at 500% Elongation	5.5Mpa max	--	4.8~5.4Mpa	--
Freedom from Holes	ASTM D5151-11		Passed Standard Acceptance Criteria Holes at Inspection Level I, AQL 2.5	
Powder residue	ASTM D6124-11, ≤ 2mg/glove		0.68 mg/glove, Meets ASTM D6124-11 Results generated values below 2mg/glove of residual powder	
Protein Content	ASTM D5712-10, ≤ 200µg/dm ² Aqueous extractable protein		Aqueous extractable protein: 70.8 mcg/dm ² , Meets ASTM D5712-10, Results generated values below 200µg/dm ² of Aqueous extractable protein content	
Biocompatibility	Primary Skin Irritation in rabbits ISO		Under the condition of the test, not an irritant.	



	10993-10:2010-08-01	
	10993-10:2010-08-01	Under the condition of the test, not a sensitizer.

• The Powdered Nitrile Patient Examination Gloves

Characteristics	Standard		Test Data	
Dimension	ASTM D6319-10			
Palm width	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	80±10	81~85	
	Medium	95±10	95~99	
	Large	110±10	110~114	
Overall Length	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	220 min	251~255	
	Medium	230 min	250~262	
	Large	230 min	259~264	
Finger Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.05 min	0.08	
	Medium	0.05 min	0.08	
	Large	0.05 min	0.08	
Palm Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.05 min	0.08	
	Medium	0.05 min	0.08	
	Large	0.05 min	0.08	
Physical Properties	ASTM D6319-10			
	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>
- Tensile Strength	14Mpa min	14Mpa min	17.5~31.1Mpa	15.7~18.5Mpa
- Ultimate Elongation	500% min	400% min	761~948%	421~839%
Freedom from Holes	ASTM D5151-11		Passed Standard Acceptance Criteria Holes at Inspection Level G-1, AQL 2.5	
Powder Amount	ASTM D6124-11, ≤ 10mg/dm ²		1.86 mg/dm ² , Meets ASTM D6124-11 Results generated values below 10mg/dm ² of residual powder	
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10:2010-08-01		Under the condition of the test, not an irritant.	
	10993-10:2010-08-01		Under the condition of the test, not a sensitizer.	

• The Powder-free Nitrile Patient Examination Gloves

Characteristics	Standard		Test Data	
Dimension	ASTM D6319-10			
Palm width	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	



	Small	80±10	81~85	
	Medium	95±10	94~99	
	Large	110±10	110~114	
Overall Length	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	220 min	252~257	
	Medium	230 min	255~260	
	Large	230 min	257~263	
Finger Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.05 min	0.08	
	Medium	0.05 min	0.08	
	Large	0.05 min	0.08	
Palm Thickness	<i>Size</i>	<i>(mm)</i>	<i>(mm)</i>	
	Small	0.05 min	0.08	
	Medium	0.05 min	0.08	
	Large	0.05 min	0.08	
Physical Properties	ASTM D6319-10			
	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>	<i>Before Aging</i>	<i>After aging at 70±2 °C 166±2 hrs</i>
- Tensile Strength	14Mpa min	14Mpa min	18.8~29.5Mpa	16.2~21.0Mpa
- Ultimate Elongation	500% min	400% min	745~945%	445~773%
Freedom from Holes	ASTM D5151-11		Passed Standard Acceptance Criteria Holes at Inspection Level G-1, AQL 2.5	
Powder residue	ASTM D6124-11, ≤ 2mg/glove		0.72 mg/glove, Meets ASTM D6124-11 Results generated values below 2mg/glove of residual powder	
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10:2010-08-01		Under the condition of the test, not an irritant.	
	Dermal sensitization in the guinea pig ISO 10993-10:2010-08-01		Under the condition of the test, not a sensitizer.	

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

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 1) ASTM D3578-10, Standard Specification for Rubber Examination Gloves.
- 2) ASTM D5151-11, Standard Test Method for Detection of Holes in Medical Gloves.
- 3) ASTM D6124-11, Standard Test Method for Residual Powder on Medical Gloves.
- 4) ASTM D5712-10, Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method.
- 5) ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.
- 6) ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

6. Substantial Equivalent Based on Assessment of Clinical Performance Data:



Clinical data was not including in this submission.

7. Substantially Equivalent Comparison Conclusion

• For Powdered Latex Patient Examination Gloves

Parameters		New Device	Predicate Device
1	510(k) Number	K150612	K072145
2	Marketing clearance date	--	Feb 26 th , 2008
3	Device Name	Annyu Powdered Latex Patient Examination Glove	Powdered Latex Patient Examination Glove
4	Manufacturer	Anhui Anyu Latex Products Co., Ltd	Zhanjiang Jiali Glove Products Co., LTD
5	Product Code	LYY	LYY
6	Regulation No.	21 CFR 880.6250	21 CFR 880.6250
7	Class	I	I
8	Intended use	A patient examination glove 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.	A patient examination glove 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.
9	Material	Natural Rubber Latex	Natural Rubber Latex
10	Design	Single use	Single use
		Non-sterile	Non-sterile
		Powdered	Powdered
		Ambidextrous	Ambidextrous
		Cuffed	Cuffed
11	Description	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.
12	Size	Provided in sizes small, medium and large	Provided in sizes small, medium and large
13	Specifications	Powdered Latex Examination Gloves Meet ASTM D3578-10	Powdered Latex Examination Gloves Meet ASTM D3578-05
14	Dimensions - Overall Length	Meets ASTM D3578-10	Meets ASTM D3578-05
		Small: 220mm min	Small: 220mm min
		Medium: 230mm min	Medium: 230mm min
		Large: 230mm min	Large: 230mm min
15	Dimensions - Palm Width	Meets ASTM D3578-10	Meets ASTM D3578-05
		Small: 80±10mm	Small: 80±10mm
		Medium: 95±10mm	Medium: 95±10mm
		Large: 111±10mm	Large: 111±10mm
16	Dimensions - Finger Thickness	Meets ASTM D3578-10 0.08mm min	Meets ASTM D3578-05 0.08mm min
	Dimensions - Palm Thickness	Meets ASTM D3578-10 0.08mm min	Meets ASTM D3578-05 0.08mm min
17	Physical Properties	Meets ASTM D3578-10	Meets ASTM D3578-05



		<p><i>Before Aging:</i></p> <ul style="list-style-type: none"> - Tensile Strength: 18Mpa min - Ultimate Elongation: 650% min - Stress at 500% Elongation: 5.5Mpa max <p>Meets ASTM D3578-10</p> <p><i>After aging at 70±2 °C 166±2 hrs:</i></p> <ul style="list-style-type: none"> - Tensile Strength: 14Mpa min - Ultimate Elongation: 500% min 	<p><i>Before Aging:</i></p> <ul style="list-style-type: none"> - Tensile Strength: 18Mpa min - Ultimate Elongation: 650% min - Stress at 500% Elongation: 5.5Mpa max <p>Meets ASTM D3578-05</p> <p><i>After aging at 70±2 °C 166±2 hrs:</i></p> <ul style="list-style-type: none"> - Tensile Strength: 14Mpa min - Ultimate Elongation: 500% min
18	Freedom from Holes	Meets ASTM D3578-10 and ASTM D5151-11 Holes at Inspection Level I, AQL 2.5	Meets ASTM D3578-05 and ASTM D5151-06
19	Powder Amount	Meets ASTM D6124-11 Below 10mg/dm ² of residual powder	Meets ASTM D6124-06 Below 10mg/dm ² of residual powder
20	Protein Content	Meets ASTM D5712-10, Below 200µg/dm ² of aqueous extractable protein content	Meets ASTM D5712-05 Below 200µg/dm ² of aqueous extractable protein content
21	Absorbable donning or dusting powder	Cornstarch, Powdered with absorbable dusting powder, U.S.P.	Cornstarch, Powdered with absorbable dusting powder, U.S.P.
22	Biocompatibility	Meets ISO 10993-10:2010; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of the test, not a sensitizer.	Meets ISO 10993-10:2006; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of the test, not a sensitizer.
23	Color	Creamy white, no colorant	Same
24	Labeling Features	Include the required labeling: <ul style="list-style-type: none"> ● Examination Gloves ● Non-sterile ● Single Use Only ● Powdered ● Ambidextrous ● Natural rubber latex ● Device color: Creamy white ● Allergy warning ● Contents, Size, Lot No. and Manufacturing Date ● Storage conditions ● Manufacturer Name and Address 	Include the required labeling: <ul style="list-style-type: none"> ● Examination Gloves ● Single Use Only ● Powdered ● Size, Serial No., Manufacturing Date and Quantity ● Natural rubber latex ● Protein Label Claims ● Allergy warning ● Manufacturer Name and Address

● For Powder-free Latex Patient Examination Gloves

Parameters		New Device	Predicate Device
1	510(k) Number	K150612	K072145
2	Marketing clearance date	--	Feb 26 th , 2008
3	Device Name	Anny Powder free Latex Patient Examination Glove	Powder free Latex Patient Examination Glove



4	Manufacturer	Anhui Anyu Latex Products Co., Ltd	Zhanjiang Jiali Glove Products Co., LTD
5	Product Code	LYY	LYY
6	Regulation No.	21 CFR 880.6250	21 CFR 880.6250
7	Class	I	I
8	Intended use	A patient examination glove 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.	A patient examination glove 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.
9	Material	Natural Rubber Latex	Natural Rubber Latex
10	Design	Single use	Single use
		Non-sterile	Non-sterile
		Powder free	Powder free
		Ambidextrous	Ambidextrous
		Cuffed	Cuffed
11	Description	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.
12	Size	Provided in sizes small, medium and large	Provided in sizes small, medium and large
13	Specifications	Powdered Latex Examination Gloves Meet ASTM D3578-10	Powdered Latex Examination Gloves Meet ASTM D3578-05
14	Dimensions - Overall Length	Meets ASTM D3578-10	Meets ASTM D3578-05
		Small: 220mm min	Small: 220mm min
		Medium: 230mm min	Medium: 230mm min
		Large: 230mm min	Large: 230mm min
15	Dimensions - Palm Width	Meets ASTM D3578-10	Meets ASTM D3578-05
		Small: 80±10mm	Small: 80±10mm
		Medium: 95±10mm	Medium: 95±10mm
		Large: 111±10mm	Large: 111±10mm
16	Dimensions - Finger Thickness	Meets ASTM D3578-10 0.08mm min	Meets ASTM D3578-05 0.08mm min
	Dimensions - Palm Thickness	Meets ASTM D3578-10 0.08mm min	Meets ASTM D3578-05 0.08mm min
17	Physical Properties	Meets ASTM D3578-10 <i>Before Aging:</i> - Tensile Strength: 18Mpa min - Ultimate Elongation: 650% min - Stress at 500% Elongation: 5.5Mpa max	Meets ASTM D3578-05 <i>Before Aging:</i> - Tensile Strength: 18Mpa min - Ultimate Elongation: 650% min - Stress at 500% Elongation: 5.5Mpa max
		Meets ASTM D3578-10 <i>After aging at 70±2 °C 166±2 hrs:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation: 500% min	Meets ASTM D3578-05 <i>After aging at 70±2 °C 166±2 hrs:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation: 500% min
18	Freedom from Holes	Meets ASTM D3578-10 and ASTM D5151-11 Holes at Inspection Level I, AQL 2.5	Meets ASTM D3578-05 and ASTM D5151-06



19	Powder residue	Meets ASTM D6124-11 Below 2mg/glove of residual powder	Meets ASTM D6124-06 Below 2mg/glove of residual powder
20	Protein Content	Meets ASTM D5712-10, Below 200µg/dm ² of aqueous soluble protein content	Meets ASTM D5712-05, Below 200µg/dm ² of aqueous soluble protein content
21	Polymer Coating	It is coated with a polyurethane based coating on the inner side to facilitate donning. Polymer name: polyurethane & polyacrylic acid	It is coated with a polyurethane based coating on the inner side to facilitate donning. Polymer name: polyurethane & polyacrylic acid
22	Biocompatibility	Meets ISO 10993-10:2010; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of the test, not a sensitizer.	Meets ISO 10993-10:2006; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of the test, not a sensitizer.
23	Color	Creamy white, no colorant	Creamy white, no colorant
24	Labeling Features	Include the required labeling: <ul style="list-style-type: none"> ● Examination Gloves ● Non-sterile ● Disposable ● Powder-free ● Ambidextrous ● Natural rubber latex ● Device color: Creamy white ● Allergy warning ● Contents, Size, Lot No. and Manufacturing Date ● Storage conditions ● Manufacturer Name and Address 	Include the required labeling: <ul style="list-style-type: none"> ● Examination Gloves ● Single Use Only ● Powder-free ● Size, Serial No., Manufacturing Date and Quantity ● Natural rubber latex ● Protein Label Claims ● Allergy warning ● Manufacturer Name and Address

● For Powdered Nitrile Patient Examination Gloves

Parameters		New Device	Predicate Device
1	510(k) Number	K150612	K072145
2	Marketing clearance date	--	Feb 26 th , 2008
3	Device Name	Annuy Powdered Nitrile Patient Examination Glove	Powdered Nitrile Patient Examination Glove
4	Manufacturer	Anhui Anyu Latex Products Co., Ltd	Zhanjiang Jiali Glove Products Co., LTD
5	Product Code	LZA	LZA
6	Regulation No.	21 CFR 880.6250	21 CFR 880.6250
7	Class	I	I
8	Intended use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and	A patient examination glove 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.	examiner.
9	Material	Nitrile Butadiene Rubber Latex	Nitrile Butadiene Rubber Latex
10	Design	Single use	Single use
		Non-sterile	Non-sterile
		Powdered	Powdered
		Ambidextrous	Ambidextrous
		Cuffed	Cuffed
11	Description	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.
12	Size	Provided in sizes small, medium and large	Provided in sizes small, medium and large
13	Specifications	Powdered Nitrile Examination Gloves Meet ASTM D6319-10	Powdered Nitrile Examination Gloves Meet ASTM D6319-05
14	Dimensions - Overall Length	Meets ASTM D6319-10 Small: 220mm min Medium: 230mm min Large: 230mm min	Meets ASTM D6319-05 Small: 220mm min Medium: 230mm min Large: 230mm min
15	Dimensions - Palm Width	Small: 80±10mm Medium: 95±10mm Large: 110±10mm Meets ASTM D6319-10	Small: 80±10mm Medium: 95±10mm Large: 110±10mm Meets ASTM D6319-05
16	Dimensions - Finger Thickness	Meets ASTM D6319-10 0.05mm min	Meets ASTM D6319-05 0.05mm min
	Dimensions - Palm Thickness	Meets ASTM D6319-10 0.05mm min	Meets ASTM D6319-05 0.05mm min
17	Physical Properties	Meets ASTM D6319-10 <i>Before Aging:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation:500% min	Meets ASTM D6319-05 <i>Before Aging:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation:500% min
		Meets ASTM D6319-10 <i>After aging at 70±2 °C 166±2 hrs:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation: 400% min	Meets ASTM D6319-05 <i>After aging at 70±2 °C 166±2 hrs:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation: 400% min
18	Freedom from Holes	Meets ASTM D6319-10 and ASTM D5151-11; Holes at Inspection Level G-1, AQL 2.5	Meets ASTM D6319-05 and ASTM D5151-06
19	Powder Amount	Meets ASTM D6124-11, Below 10mg/dm ²	Meets ASTM D6124-06 Below 10mg/dm ² of residual powder
20	Absorbable donning or dusting powder	Cornstarch, Powdered with absorbable dusting powder, U.S.P.	Cornstarch, Powdered with absorbable dusting powder, U.S.P.
21	Biocompatibility	Meets ISO 10993-10:2010; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of the	Meets ISO 10993-10:2006; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of



		test, not a sensitizer.	the test, not a sensitizer.
22	Color	Blue Chemical characterization: Copper Phthalocyanine β modification	Blue Chemical characterization: Copper Phthalocyanine β modification
23	Labeling Features	Include the required labeling: <ul style="list-style-type: none"> • Nitrile Examination Gloves • Non-sterile • Disposable • Powdered • Ambidextrous • Device color: Blue • Contents, Size, Lot No. and Manufacturing Date • Storage conditions • Manufacturer Name and Address 	Include the required labeling: <ul style="list-style-type: none"> • Nitrile Examination Gloves • Single Use Only • Powdered • Size, Serial No., Manufacturing Date and Quantity • Manufacturer Name and Address

• For Powder-free Nitrile Patient Examination Gloves

Parameters		New Device	Predicate Device
1	510(k) Number	K150612	K072145
2	Marketing clearance date	--	Feb 26 th , 2008
3	Device Name	Anny Powder-free Nitrile Patient Examination Glove	Powder-free Nitrile Patient Examination Glove
4	Manufacturer	Anhui Anyu Latex Products Co., Ltd	Zhanjiang Jiali Glove Products Co., LTD
5	Product Code	LZA	LZA
6	Regulation No.	21 CFR 880.6250	21 CFR 880.6250
7	Class	I	I
8	Intended use	A patient examination glove 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.	A patient examination glove 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.
9	Material	Nitrile Butadiene Rubber Latex	Nitrile Butadiene Rubber Latex
10	Design	Single use	Single use
		Non-sterile	Non-sterile
		Powder-free	Powder-free
		Ambidextrous	Ambidextrous
		Cuffed	Cuffed
11	Description	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.
12	Size	Provided in sizes small, medium and large	Provided in sizes small, medium and large
13	Specifications	Powder-free Nitrile Examination Gloves Meet ASTM D6319-10	Powder-free Nitrile Examination Gloves Meet ASTM D6319-05



14	Dimensions - Overall Length	Meets ASTM D6319-10 Small: 220mm min Medium: 230mm min Large: 230mm min	Meets ASTM D6319-05 Small: 220mm min Medium: 230mm min Large: 230mm min
15	Dimensions - Palm Width	Meets ASTM D6319-10 Small: 80±10mm Medium: 95±10mm Large: 110±10mm	Meets ASTM D6319-05 Small: 80±10mm Medium: 95±10mm Large: 110±10mm
16	Dimensions - Finger Thickness	Meets ASTM D6319-10 0.05mm min	Meets ASTM D6319-05 0.05mm min
	Dimensions - Palm Thickness	Meets ASTM D6319-10 0.05mm min	Meets ASTM D6319-05 0.05mm min
17	Physical Properties	Meets ASTM D6319-10 <i>Before Aging:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation:500% min	Meets ASTM D6319-05 <i>Before Aging:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation:500% min
		Meets ASTM D6319-10 <i>After aging at 70±2 °C 166±2 hrs:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation: 400% min	Meets ASTM D6319-05 <i>After aging at 70±2 °C 166±2 hrs:</i> - Tensile Strength: 14Mpa min - Ultimate Elongation: 400% min
18	Freedom from Holes	Meets ASTM D6319-10 and ASTM D5151-11; Holes at Inspection Level G-1, AQL 2.5	Meets ASTM D6319-05 and ASTM D5151-06
19	Powder residue	Meets ASTM D6124-11 Below 2mg/glove of residual powder	Meets ASTM D6124-06 Below 2mg/glove of residual powder
20	Polymer Coating	It is coated with a polyurethane based coating on the inner side to facilitate donning. Polymer name: polyurethane & polyacrylic acid	It is coated with a polyurethane based coating on the inner side to facilitate donning. Polymer name: polyurethane & polyacrylic acid
21	Biocompatibility	Meets ISO 10993-10:2010; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of the test, not a sensitizer.	Meets ISO 10993-10:2006; Skin Irritation: Under the condition of the test, not an irritant. Skin Sensitization: Under the condition of the test, not a sensitizer.
22	Color	Blue Chemical characterization: Copper Phthalocyanine β modification	Blue Chemical characterization: Copper Phthalocyanine β modification
23	Labeling Features	Include the required labeling: ● Nitrile Examination Gloves ● Non-sterile ● Disposable ● Powder-free ● Ambidextrous ● Device color: Blue	Include the required labeling: ● Nitrile Examination Gloves ● Single Use Only ● Powder-free ● Size, Serial No., Manufacturing Date and Quantity ● Manufacturer Name and Address



		<ul style="list-style-type: none"> ● Contents, Size, Lot No. and Manufacturing Date ● Storage conditions ● Manufacturer Name and Address 	
--	--	---	--

Discussion: Based on the above comparison, the Annuy Latex Examination Gloves (Powdered and Powder-Free), Annuy Nitrile Examination Gloves (Powdered and Powder-Free) and the predicate device have same technology characteristics such as material, design, intended use, specification and performance features.

Both the subject device and predicate device meet the technology characteristics of ASTM D3578, ASTM D6319 and ISO10993-10 standards. From the tests, results generated values that,

Annuy Powdered Latex Examination Gloves contain no more than 10mg/dm² powder and no more than 200µg/dm² extractable protein.

Annuy Powder-free Latex Examination Gloves contain no more than 2mg/glove of residual powder and no more than 200µg/dm² extractable protein.

Annuy Powdered Nitrile Examination Gloves contain no more than 10mg/dm² powder.

Annuy Powder-free Nitrile Examination Gloves contain no more than 2mg/glove of residual powder.

Conclusion: The Annuy Latex Examination Gloves (Powdered and Powder-Free) and Nitrile Examination Gloves (Powdered and Powder-Free) manufactured by Anhui Anyu Latex Products Co., Ltd are substantially equivalent to the predicate device (K072145).