DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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: K150609
Trade/Device Name: Annuy Latex Surgeon's Gloves (Powdered and Powder Free)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's glove
Regulatory Class: Class I
Product Code: KGO
Dated: October 6, 2015
Received: October 14, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Annuy Latex Surgeon's Gloves (Powdered and Powder Free)

Indications for Use *(Describe)*
A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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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Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K150609
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

2. Device Description:

Proprietary Name:	Annuy Latex Surgeon's Gloves (Powdered and Powder Free)
Common Name:	Surgical Gloves
Classification Name:	surgeon's gloves
Product Code:	Surgeon's Glove - 79KGO
Device Class:	I
Regulation Number:	21 CFR 878.4460
Review Panel:	General & Plastic Surgery
Indications for use:	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
Device Description:	The proposed device, Latex Surgeon's Gloves (Powdered and Powder Free) is a sterilized and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination. The proposed device is made of natural rubber latex, per standard ASTM D3577-09e1, the rubber surgical gloves classification is: “Type I - gloves compounded primarily from natural rubber latex”. The proposed device includes Powdered and Powder Free Latex Surgeon's Gloves, and variations of different size. All variations share the same color, creamy white. The proposed device is provided radiation sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and place in a sterility maintenance package to ensure a shelf life of 3 years.

3. Predicate Device Identification

510(k) Number: K130301
Clearing date: August 22, 2013
Product Name: Latex Surgeon's Gloves (Powdered and Powder Free)

4. Performance Test Data Summary

● The Powdered Latex Surgeon's Gloves

Characteristics	Standard		Test Data
Dimension	ASTM 3577-09^{e1}		
Palm width	*Size*	*(mm)*	*(mm)*
	6	76±6	76~80
	6*1/2*	83±6	82~88
	7	89±6	88~94
	7*1/2*	95±6	99~101
	8	102±6	100~105
	8*1/2*	108±6	107~111
	9	114±6	112~115
Overall Length	*Size*	*(mm)*	*(mm)*
	6	265 min	267~272
	6*1/2*	265 min	271~275
	7	265 min	272~278
	7*1/2*	265 min	272~281
	8	265 min	278~282
	8*1/2*	265 min	280~284
	9	265 min	286~289
Finger Thickness	*Size*	*(mm)*	*(mm)*
	6	0.10 min	0.10~0.12
	6*1/2*	0.10 min	0.10~0.13
	7	0.10 min	0.11~0.13
	7*1/2*	0.10 min	0.10~0.13
	8	0.10 min	0.10~0.13
	8*1/2*	0.10 min	0.10~0.12
	9	0.10 min	0.10~0.13
Palm Thickness	*Size*	*(mm)*	*(mm)*
	6	0.10 min	0.10~0.12
	6*1/2*	0.10 min	0.10~0.13
	7	0.10 min	0.11~0.13
	7*1/2*	0.10 min	0.10~0.13
	8	0.10 min	0.10~0.13
	8*1/2*	0.10 min	0.11~0.13
	9	0.10 min	0.11~0.13
Cuff thickness	*Size*	*(mm)*	*(mm)*
	6	0.10 min	0.10~0.12
	6*1/2*	0.10 min	0.10~0.12
	7	0.10 min	0.11~0.13
	7*1/2*	0.10 min	0.10~0.13
	8	0.10 min	0.10~0.12

	8*1/2*	0.10 min	0.10~0.13	
	9	0.10 min	0.10~0.13	
Physical Properties	ASTM 3577-09e1			
	Before Aging	*After aging at 70±2 ℃ 166±2 hrs*	*Before Aging*	*After aging at 70±2 ℃ 166±2 hrs*
- Tensile Strength	24MPa,min	18MPa,min	24.5-35.2Mpa	23.3-27.8Mpa
- Ultimate Elongation	750% min	560% min	1012%-1258%	848%-1036%
- Stress at 500% Elongation	5.5MPa,max	--	4.3~4.7Mpa	--
Freedom from Holes	ASTM D5151-11		Passed Standard Acceptance Criteria Holes at Inspection Level I, AQL 1.5	
Powder Amount	ASTM D6124-11, ≦15mg/dm^2		1.43 mg/dm^2, Meets ASTM D6124-06(Reapproved 2011), Results generated values below 15mg/dm^2 of Powder amount	
Protein Content	ASTM D5712-10, ≦200μg/dm^2 Aqueous extractable protein		Aqueous extractable protein: 132 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.	
Sterilization Validation	ISO 11137-1:2006		Sterility Assurance Level (SAL) of 10^{-6}	

● The Powder-free Latex Surgeon's Gloves

Characteristics	**Standard**		**Test Data**
Dimension	ASTM 3577-09e1		
Palm width	*Size*	*(mm)*	*(mm)*
	6	76±6	76~81
	6*1/2*	83±6	81~87
	7	89±6	87~93
	7*1/2*	95±6	99~101
	8	102±6	100~104
	8*1/2*	108±6	106~110
	9	114±6	111~115
Overall Length	*Size*	*(mm)*	*(mm)*
	6	265 min	268~275
	6*1/2*	265 min	270~276
	7	265 min	270~278
	7*1/2*	265 min	272~281
	8	265 min	278~284

	8*1/2*	265 min	280~285	
	9	265 min	284~289	
Finger Thickness	*Size*	*(mm)*	*(mm)*	
	6	0.10 min	0.10~0.12	
	6*1/2*	0.10 min	0.10~0.12	
	7	0.10 min	0.11~0.12	
	7*1/2*	0.10 min	0.10~0.13	
	8	0.10 min	0.10~0.12	
	8*1/2*	0.10 min	0.10~0.12	
	9	0.10 min	0.10~0.13	
Palm Thickness	*Size*	*(mm)*	*(mm)*	
	6	0.10 min	0.10~0.13	
	6*1/2*	0.10 min	0.10~0.13	
	7	0.10 min	0.10~0.12	
	7*1/2*	0.10 min	0.10~0.13	
	8	0.10 min	0.11~0.12	
	8*1/2*	0.10 min	0.11~0.12	
	9	0.10 min	0.10~0.12	
Cuff thickness	*Size*	*(mm)*	*(mm)*	
	6	0.10 min	0.10~0.12	
	6*1/2*	0.10 min	0.10~0.12	
	7	0.10 min	0.10~0.12	
	7*1/2*	0.10 min	0.10~0.13	
	8	0.10 min	0.10~0.12	
	8*1/2*	0.10 min	0.10~0.12	
	9	0.10 min	0.10~0.12	
Physical Properties	ASTM 3577-09^{e1}			
	Before Aging	*After aging at 70±2 ℃ 166±2 hrs*	*Before Aging*	*After aging at 70±2 ℃ 166±2 hrs*
- Tensile Strength	24MPa,min	18MPa,min	24.1-40.8Mpa	20.8-27.4Mpa
- Ultimate Elongation	750% min	560% min	961%-1239%	761%-1103%
- Stress at 500% Elongation	5.5MPa,max	--	4.3~4.7Mpa	--
Freedom from Holes	ASTM D5151-11		Passed Standard Acceptance Criteria Holes at Inspection Level I, AQL 1.5	
Powder residue	ASTM D6124-11, ≦2mg/glove		0.6 mg/glove, Meets ASTM D6124-06(Reapproved 2011),Results generated values below 2mg of residual powder	
Protein Content	ASTM D5712-10, ≦200μg/dm^2 Aqueous extractable protein		Aqueous extractable protein:61.6 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.
Sterilization Validation	ISO 11137-1:2006	Sterility Assurance Level (SAL) of 10^{-6}

5. Non-Clinical Test Conclusion

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:

* ASTM D3577-09^{e1}, Standard Specification for Rubber Surgical Gloves
* ASTM D5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves
* ASTM D6124-06, (Reaffirmation 2011) Standard Test Method for Residual Powder on Medical Gloves
* ASTM D6499-12, Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products
* ASTM D5712-10, Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method
* ISO 11137-1:06, Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process For Medical Devices (Sterility)
* ISO 11137-2:13, Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose. (Sterility)
* ASTM F1929-12, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration (Sterility)
* ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials (Sterility)
* ASTM F1608:09, Standard Test Method For Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method) (Sterility)
* ASTM D7161-05(Reapproved 2010),Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
* ISO 10993-10:10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Biocompatibility)

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 Surgeon's Gloves

Parameters		**New Device**	**Predicate Device**
1	510(k) Number	K150609	K130301
2	Marketing clearance date	--	AUG 22,2013
3	Device Name	Annuy Powdered Latex Surgeon's Gloves	Powdered Latex Surgeon's Gloves
4	Manufacturer	Anhui Anyu Latex Products Co., Ltd	ELIMEDICAL DEVICES (FUJIAN) INC.
5	Product Code	KGO	KGO
6	Regulation No.	21 CFR 878.4460	21 CFR 878.4460

7	Class	I	I
8	Device description	Annuy Powdered Latex Surgeon's Gloves are Type I - gloves compounded primarily from natural rubber latex, and variations of different size. All variations share the same color, creamy white.	Powdered Latex Surgeon's Gloves are Type I - gloves compounded primarily from natural rubber latex, and variations of different size. All variations share the same color, creamy white.
9	Intended use	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
10	Material	Natural Rubber Latex	Natural Rubber Latex
11	Design	Single use	Single use
		Sterile(Gamma radiation, SAL:10^{-6})	Sterile(Gamma radiation, SAL:10^{-6})
		Powdered	Powdered
		Cuffed	Cuffed
12	Size	Provided in sizes 6,6*1/2*, 7, 7*1/2*, 8, 8*1/2*,9	Provided in sizes 6,6*1/2*, 7, 7*1/2*, 8, 8*1/2*,9
13	Specifications	Powdered Latex Examination Gloves Meet ASTM D3577-09^{e1}	Powdered Latex Examination Gloves Meet ASTM D3577-09^{e1}
14	Dimensions - Overall Length	Meets ASTM D3577-09^{e1} 265mm min	Meets ASTM D3577-09^{e1} 265mm min
15	Dimensions - Palm Width	Meets ASTM D3577-09^{e1} 6 76±6mm 6*1/2* 83±6mm 7 89±6mm 7*1/2* 95±6mm 8 102±6mm 8*1/2* 108±6mm 9 114±6mm	Meets ASTM D3577-09^{e1} 6 76±6mm 6*1/2* 83±6mm 7 89±6mm 7*1/2* 95±6mm 8 102±6mm 8*1/2* 108±6mm 9 114±6mm
16	Dimensions - Finger Thickness	Meets ASTM D3577-09^{e1} 0.10mm min	Meets ASTM D3577-09^{e1} 0.10mm min
	Dimensions - Palm Thickness	Meets ASTM D3577-09^{e1} 0.10mm min	Meets ASTM D3577-09^{e1} 0.10mm min
	Dimensions - Cuff Thickness	Meets ASTM D3577-09^{e1} 0.10mm min	Meets ASTM D3577-09^{e1} 0.10mm min
17	Physical Properties	Meets ASTM D3577-09^{e1} *Before Aging:* - Tensile Strength: 24Mpa min - Ultimate Elongation: 750% min - Stress at 500% Elongation: 5.5Mpa max	Meets ASTM D3577-09^{e1} *Before Aging:* - Tensile Strength: 24Mpa min - Ultimate Elongation: 750% min - Stress at 500% Elongation: 5.5Mpa max
		Meets ASTM D3578-10 *After aging at 70±2℃ 166±2 hrs:* - Tensile Strength: 18Mpa min - Ultimate Elongation: 560% min	Meets ASTM D3578-10 *After aging at 70±2℃ 166±2 hrs:* - Tensile Strength: 18Mpa min - Ultimate Elongation: 560% min
18	Freedom from	Meets ASTM D3577-09^{e1} and ASTM	Meets ASTM D3577-09^{e1} and ASTM

	Holes	D5151-11 Holes at Inspection Level I, AQL 1.5	D5151-11 Holes at Inspection Level I, AQL 1.5
19	Powder Amount	Meets ASTM D6124-11 Below 15mg/dm^2 of residual powder	Meets ASTM D6124-11 Below 15mg/dm^2 of residual powder
20	Protein Content	Meets ASTM D5712-10, Below 200μg/dm^2 of aqueous extractable protein content	Meets ASTM D5712-10, 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 10993-10:2010; **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: ● Surgical Gloves ● Sterile ● Single Use Only ● Powdered ● Natural rubber latex ● Device color: Creamy white ● Allergy warning ● Contents, Size, REF, Lot Number, MFG date, expiration data ● Storage conditions ● Manufacturer Name and Address	Include the required labeling: ● Surgical Gloves ● Sterile ● Single Use Only ● Powdered ● Natural rubber latex ● Device color: Creamy white ● Allergy warning ● Contents, Size, Lot Number, MFG date ● Storage conditions ● Manufacturer and distributor Name and Address

● For Powder-free Latex Surgeon's Gloves

Parameters		**New Device**	**Predicate Device**
1	510(k) Number	K150609	K130301
2	Marketing clearance date	--	AUG 22,2013
3	Device Name	Annuy Powder-free Latex Surgeon's Gloves	Powder-free Latex Surgeon's Gloves
4	Manufacturer	Anhui Anyu Latex Products Co., Ltd	ELIMEDICAL DEVICES (FUJIAN) INC.
5	Product Code	KGO	KGO
6	Regulation No.	21 CFR 878.4460	21 CFR 878.4460
7	Class	I	I
8	Device description	Annuy Powder-free Latex Surgeon's Gloves are Type I - gloves compounded primarily from natural rubber latex, and variations of different size. All variations share the same color, creamy white.	Powder-free Latex Surgeon's Gloves are Type I - gloves compounded primarily from natural rubber latex, and variations of different size. All variations share the same color, creamy white.
9	Intended use	A latex surgeon's glove is a device made of	A latex surgeon's glove is a device made of

		natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
10	Material	Natural Rubber Latex	Natural Rubber Latex
11	Design	Single use	Single use
		Sterile(Gamma radiation, SAL:10^{-6})	Sterile(Gamma radiation, SAL:10^{-6})
		Powder-free	Powder-free
		Cuffed	Cuffed
12	Size	Provided in sizes 6,6*1/2*, 7, 7*1/2*, 8, 8*1/2*,9	Provided in sizes 6,6*1/2*, 7, 7*1/2*, 8, 8*1/2*,9
13	Specifications	Powdered Latex Examination Gloves Meet ASTM D3577-09^{e1}	Powdered Latex Examination Gloves Meet ASTM D3577-09^{e1}
14	Dimensions - Overall Length	Meets ASTM D3577-09^{e1} 265mm min	Meets ASTM D3577-09^{e1} 265mm min
15	Dimensions - Palm Width	Meets ASTM D3577-09^{e1} 6 76±6mm 6*1/2* 83±6mm 7 89±6mm 7*1/2* 95±6mm 8 102±6mm 8*1/2* 108±6mm 9 114±6mm	Meets ASTM D3577-09^{e1} 6 76±6mm 6*1/2* 83±6mm 7 89±6mm 7*1/2* 95±6mm 8 102±6mm 8*1/2* 108±6mm 9 114±6mm
16	Dimensions - Finger Thickness	Meets ASTM D3577-09^{e1} 0.10mm min	Meets ASTM D3577-09^{e1} 0.10mm min
	Dimensions - Palm Thickness	Meets ASTM D3577-09^{e1} 0.10mm min	Meets ASTM D3577-09^{e1} 0.10mm min
	Dimensions - Cuff Thickness	Meets ASTM D3577-09^{e1} 0.10mm min	Meets ASTM D3577-09^{e1} 0.10mm min
17	Physical Properties	Meets ASTM D3577-09^{e1} *Before Aging:* - Tensile Strength: 24Mpa min - Ultimate Elongation: 750% min - Stress at 500% Elongation: 5.5Mpa max	Meets ASTM D3577-09^{e1} *Before Aging:* - Tensile Strength: 24Mpa min - Ultimate Elongation: 750% min - Stress at 500% Elongation: 5.5Mpa max
		Meets ASTM D3578-10 *After aging at 70±2℃ 166±2 hrs:* - Tensile Strength: 18Mpa min - Ultimate Elongation: 560% min	Meets ASTM D3578-10 *After aging at 70±2℃ 166±2 hrs:* - Tensile Strength: 18Mpa min - Ultimate Elongation: 560% min
18	Freedom from Holes	Meets ASTM D3577-09^{e1} and ASTM D5151-11 Holes at Inspection Level I, AQL 1.5	Meets ASTM D3577-09^{e1} and ASTM D5151-11 Holes at Inspection Level I, AQL 1.5
19	Powder residue	Meets ASTM D6124-11 Below 2mg/glove of residual powder	Meets ASTM D6124-11 Below 2mg/glove of residual powder
20	Protein Content	Meets ASTM D5712-10, Below 200μg/dm^2 of aqueous extractable protein content	Meets ASTM D5712-10, Below 200μg/dm^2 of aqueous extractable 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 10993-10:2010; **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: ● Surgical Gloves ● Sterile ● Single Use Only ● Powder-free ● Natural rubber latex ● Device color: Creamy white ● Allergy warning ● Contents, Size, REF, Lot Number, MFG date, expiration data ● Storage conditions ● Manufacturer Name and Address	Include the required labeling: ● Surgical Gloves ● Sterile ● Single Use Only ● Powder-free ● Natural rubber latex ● Device color: Creamy white ● Allergy warning ● Contents, Size, Lot Number, MFG date ● Storage conditions ● Manufacturer and distributor Name and Address

Discussion: Based on the above comparison, the Annuy Latex Surgeon's 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 D3577 and ISO10993-10 standards. From the tests, results generated values that,

Annuy Powdered Latex Surgeon's Gloves contain no more than 15mg/dm^2 powder and no more than 200μg/dm^2 extractable protein.

Annuy Powder-free Latex Surgeon's Gloves contain no more than 2mg/glove of residual powder and no more than 200μg/dm^2 extractable protein.

Conclusion: The Annuy Latex Surgeon's Gloves (Powdered and Powder Free) manufactured by Anhui Anyu Latex Products Co., Ltd are substantially equivalent to the predicate device (K130301).