February 22, 2023

Shandong Intco Medical Products Co, Ltd.
% Ivy Wang
Consultant
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K223298
Trade/Device Name: Sterile Latex Examination Gloves Powder Free (S, M, L, Extra L)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: January 10, 2023
Received: January 12, 2023

Dear Ivy Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian M.D., Ph. D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223298

Device Name

Sterile Latex Examination Gloves Powder Free (S, M, L, Extra L)

Indications for Use *(Describe)*

The Sterile Latex Examination Gloves Powder Free is a disposable device intended for medical purposes that is worn on the examiners' 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 - K223298

(As requirement by 21 CFR 807.92)

Date prepared: 2023-02-22

A. Applicant:

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B. Device:

Trade Name: Sterile Latex Examination Gloves Powder Free (S, M, L, Extra L)
Common Name: Latex Patient Examination Gloves (Powder Free)

Regulatory Information
Classification Name: Latex Patient Examination Glove
Classification: Class I
Product code: LYY
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

C. Predicate device:

K171367
SANCARE STERILE LATEX EXAMINATION GLOVES
Sanrea Healthcare Products Pvt Ltd

D. Indications for use of the device:

The Sterile Latex Examination Gloves Powder Free is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.

E. Device Description:

The Sterile Latex Examination Gloves Powder Free are natural color, single use only, disposable examination gloves intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The device is ambidextrous and can be worn on either the left or right hand. The gloves are offered in sizes small, medium, large and extra-large, and sterilized by Gamma radiation.

The gloves are designed and manufactured in accordance with the ASTM D3578-19 standard.

F. Summary of Technological Characteristics

Table 1 General Comparison of Proposed and Predicate Devices

Device	**Proposed Device**	**Predicate Device**	**Result**
510K #	K223298	K171367	-
Product Name	Sterile Latex Examination Gloves Powder Free	SANCARE STERILE LATEX EXAMINATION GLOVES	-
Product Code	LYY	LYY	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for use	The Sterile Latex Examination Gloves Powder Free is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.	The Sterile Latex Examination Gloves, Powder Free, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.	Same
Powder free	Yes	Yes	Same
Design feature	Ambidextrous	Ambidextrous	Same
Material	Natural Rubber Latex	Natural Rubber Latex	Same
OTC use	Yes	Yes	Same
Sterility	Gamma sterilized	Ethylene Oxide sterilized	Different
Use	Singe use	Single use	Same

Analysis: The proposed device uses a different sterilization method than the predicate device. But both sterilization methods are current commonly used sterilization methods and the sterilization process validation has been conducted to demonstrate its effectiveness. Therefore, this difference does not raise any new safety or performance questions.

Table 2 Device dimension comparison

	Designation	Size					Tolerance
		XS	S	M	L	XL	
Predicate device (K171367)	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	85	111	120	±10
	Thickness, mm						
	Finger	0.08					min
	Palm	0.08					min

	Designation	Size				Tolerance
		S	M	L	XL	
Proposed device (K223298)	Length, mm	220	230	230	230	min
	Width, mm	80	95	111	120	±10
	Thickness, mm					
	Finger	0.08				min
	Palm	0.08				min
Result	Similar					

Analysis: The physical dimensions are slightly different from that of the predicate, but they all meet the requirements of ASTM D3578-19, so the differences do not raise any new safety or performance questions.

Table 3 Performance comparison

Item			**Proposed device (K223298)**	**Predicate device (K171367)**	**Result**
Color			Nature	Nature	Same
Physical properties	Before aging	Tensile strength	18MPa, min	18MPa, min	Same
		Ultimate elongation	650%, min	650%, min	Same
		Stress at 500% Elongation	5.5 MPa, Max	5.5 MPa, Max	Same
	After aging	Tensile strength	14MPa, min	14MPa, min	Same
		Ultimate elongation	500%, min	500%, min	Same
	Comply with ASTM D3578			Comply with ASTM D3578	Same
Freedom from holes			Be free from holes when tested in accordance with ASTM D3578 & ASTM D5151 G-1, AQL 1.5	Be free from holes when tested in accordance with ASTM D3578 & ASTM D5151 G-1, AQL 2.5	Different
Residual Powder			Meet the requirements of ASTM D3578 & ASTM D6124 Less than 2 mg per glove	Meet the requirements of ASTM D3578 & ASTM D6124 Less than 2 mg per glove	Same
Residual Protein			Meet the requirements of ASTM D3578 & ASTM D5712 Less than 200μg/dm²	Meet the requirements of ASTM D3578 & ASTM D5712 Less than 200μg/dm²	Same

Analysis: The subject device tested the leakage performance with a different AQL as compared to the predicate device. A more stringent acceptance criterion does not affect the safety and performance of the proposed device.

Table 4 safety comparison

Item	**Proposed device**	**Predicate device**	**Result**

		(K223298)	(K171367)	
Material		Natural rubber latex	Natural rubber latex	Same
Biocompatibility	Irritation ISO 10993-10	Under the conditions of the study, not an irritant. Comply with ISO 10993-10.	Comply with ISO 10993-10	Same
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer. Comply with ISO 10993-10.		
	Acute systemic toxicity ISO 10993-11	Under the conditions of the study, the device does not induce acute systemic toxicity response.	/	Different

Analysis: Toxicity information for the predicate device is not publicly available. This does not raise different safety or performance questions since the subject device has acceptable biocompatibility per the biocompatibility endpoint assessment.

G. Summary of Non-Clinical Testing

➢ **Biocompatibility**

The following tests for the subject device were conducted to evaluated the biocompatibility of Sterile Latex Examination Gloves Powder Free:

- ISO 10993-10: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-11: Acute Systemic Toxicity

➢ **Performance Testing**

Physical performance testing of the proposed device was conducted as per ASTM D3578-19 *Standard Specification for Rubber Examination Gloves.*

To summarize, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- ASTM D3578-19 Standard Specification for Rubber Examination Gloves
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D5712-15 Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber in Latex Natural Rubber and Elastomeric Products Using the Modified Lowry Method

Test Method	Purpose	Acceptance Criteria	Results
Dimensions (width)	The purpose of the	Width 80±10mm for Small size	Pass

(thickness)	test is to evaluate the physical dimension of the glove	95±10mm for Medium size 105±10mm for Large size 115±10mm for Extra large size Length 230mm min	81mm min for S 95mm min for M 106mm min for L 115mm min for Extra L 238mm min length
		Palm – 0.08mm min. Finger–0.08mm min.	Pass Palm – 0.11mm min. Finger–0.11mm min
Physical properties	The purpose of the test is to evaluate the tensile strength and ultimate elongation before and after aging	Before Aging: Tensile Strength: 18 MPa, min. Elongation: 650%, min. Stress at 500% Elongation: 5.5MPa, max. After Aging: Tensile Strength: 14 MPa, min. Elongation: 500%, min.	Pass Before Aging: Tensile Strength: 23.4MPa, min. Elongation: 650%, min. Stress at 500% Elongation: 5.3MPa, max. After Aging: Tensile Strength: 22MPa, min. Elongation: 704%, min.
Freedom from holes	The purpose of the test is to detect holes in the gloves	No leakage at sampling level of G-1, AQL 1.5	Pass No leakage, 314 of 315 passed
Residual Powder	The purpose of the test is to detect the powder residue in the glove	<2mg per glove	Pass average 0.09 mg per glove
Residual Protein	The purpose of the test is to detect the protein residue in the glove	<200μg/dm²	Pass Average 70.880ug/dm^2
Sterility	The purpose of the test is to detect the sterility of the glove	Sterile	Pass Sterile
Irritation ISO 10993-10	The purpose of the testing is to demonstrate the safety of the subject device.	Under the conditions of the study, not an irritant. Comply with ISO 10993-10.	Under the conditions of the study, not an irritant. Comply with ISO 10993-10.
Sensitization ISO 10993-10		Under the conditions of the study, not a sensitizer. Comply with ISO 10993-10.	Under the conditions of the study, not a sensitizer. Comply with ISO 10993-10.
Acute systemic toxicity ISO 10993-11		Under the conditions of the study, the device does not induce acute systemic toxicity response.	Under the conditions of the study, the device does not induce acute systemic toxicity response.

- **Sterilization**

The proposed device is provided Gamma sterilized to achieve the sterility Assurance Level (SAL) of 10^{-6}. The sterilization process validation was conducted in accordance with ISO 11137-1 Sterilization of health care products Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, and ISO11137-2 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Sterile Latex Examination Gloves Powder Free are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K171367.