March 25, 2022

Guangdong Jiali Pharmaceutical Co.,Ltd
℅ Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huang District
Guangzhou, Guangdong
China

Re: K213848
Trade/Device Name: Medical nitrile examination gloves (Model: JL001)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 14, 2022
Received: February 18, 2022

Dear Cassie Lee:

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, M.D., Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213848

Device Name
Medical nitrile examination gloves (Model: JL001)

Indications for Use *(Describe)*
The Medical nitrile examination gloves is intended to be worn on the hands of examiners to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

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.

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510(k) Summary K213848

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary prepared: March 15, 2022

2. Submitter's Information

Sponsor Name: Guangdong Jiali Pharmaceutical Co.,Ltd
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Application Correspondent:
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Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8200 6973
Email: regulatory@share-info.com

3. Subject Device Information

Type of 510(k): Traditional
Common Name: Polymer Patient Examination Glove
Classification Name: Non-powdered patient examination glove
Trade Name: Medical nitrile examination gloves
Model Name: JL001
Review Panel: General Hospital
Product Code: LZA
Regulation Number: 21 CFR 880.6250
Regulatory Class: Class I

4. Predicate Device Information

Sponsor: Guang Dong Kingfa SCI. & TECH.CO., LTD.
Common Name: Polymer Patient Examination Glove

Classification Name: Non-Powdered Patient Examination Glove
Trade Name: Patient Examination Gloves
510(k) Number: K203593
Review Panel: General Hospital
Product Code: LZA
Regulation Number: 21 CFR 880.6250
Regulatory Class: Class I

5. Device Description

The subject device is a powder-free nitrile examination glove, provided as a non-sterile and disposable device. The subject device is mainly made from nitrile and there are four sizes, including small (S), medium (M), large (L), X-large (XL) for optional. The gloves are provided with blue color, the colorant is Pigment Blue (CAS No.147-14-8). The examination glove is a smooth surface and has a rolled rim at the cuff edge.

6. Intended Use / Indications for Use

The Medical nitrile examination gloves is intended to be worn on the hands of examiners to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

7. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate Device	Result
Company	Guangdong Jiali Pharmaceutical Co.,Ltd	Guang Dong Kingfa SCI. & TECH.CO., LTD.	--
510 (k) Number	K213848	K203593	--
Trade Name	Medical nitrile examination gloves	Patient Examination Gloves	--
Product Code	LZA	LZA	
Classification Name	Non-Powdered Patient Examination Glove	Non-Powdered Patient Examination Glove	Same
Classification	Class I	Class I	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Indications For Use	The Medical nitrile examination gloves is intended to be worn on the hands of examiners to prevent contamination between patient and examiner. This is a	The nitrile examination glove is intended to be worn on the hands of examiners to prevent contamination between patient and examiner. This is a single-	Same

Elements of Comparison	Subject Device	Predicate Device	Result
	single-use, powder-free, non-sterile device.	use, powder-free, non-sterile device.	
Material of Use	Nitrile rubber	Nitrile rubber	Same
Color	Blue	Blue	Same
Texture	No	Finger Textured	Different Note
Size (ASTM D6319-19)	Small, Medium, Large, X Large	Small, Medium, Large, X Large	Same
Sterilization	Non-sterile	Non-sterile	Same
Usage	Single usage	Single usage	Same
Dimensions (ASTM D6319-19)	**Length:** For S: ≥220 mm For M/L/XL: ≥230 mm	**Length:** S (220mm min) M (230mm min) L (230mm min) XL (230mm min)	Same
	Width: For S: 80±10mm For M: 95±10 mm For L: 110±10 mm For XL: 120±10 mm	**Palm width:** Small (80±10mm) Medium (95±10mm) Large (110±10mm) X large (120±10mm)	
Physical Properties (ASTM D6319-19)	Meets requirements of the ASTM D6319-19 **Before Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥500%	Meets requirements of the ASTM D6319-19 **Before Aging:** Tensile Strength: Min 14 Mpa Ultimate Elongation: Min 500%	Same
	Meets requirements of the ASTM D6319-19 **After Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥400%	Meets requirements of the ASTM D6319-19 **After Aging:** Tensile Strength: Min 14Mpa Ultimate Elongation: Min 400%	
Thickness (ASTM D6319-19)	Palm min. 0.05 mm Finger min. 0.05 mm	Palm min. 0.05 mm Finger min. 0.05 mm	Same
Powder Free (ASTM D6319-19)	≤2 mg/glove	≤2 mg/glove	Same

Elements of Comparison	Subject Device	Predicate Device	Result
Freedom from Holes (Water Tight -1000 ml)-ASTM D6319-19 (Cross Reference D5151)	Meets requirements of the ASTM D6319-19	Meets requirements of the ASTM D6319-19	Same
Biocompatibility - Skin Sensitization (ISO 10993-10:2010)	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
Biocompatibility - Skin Irritation (ISO 10993-10:2010)	Under the conditions of study not an irritant	Under the conditions of study not an irritant	Same
Biocompatibility - Acute Systemic Toxicity (ISO 10993-11: 2017)	Cytotoxicity is assessed via rationale. Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	Cytotoxicity is assessed via rationale. Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	Same

Comparison in Detail(s):

Note:

Although the subject device has no texture, which is different from the predicate device, both the performance of the subject device and predicate device met the requirements of the standard ASTM D6319-19. So, the difference between the subject device and predicate device will not affect the safety and effectiveness.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary:

Test Method	Test Purpose	Acceptance Criteria	Test Results	Conclusion
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical	To determine the width, length, and thickness of the gloves	**Width:** For S: 80±10mm For M: 95±10mm For L: 110±10mm For XL: 120±10mm	**Lot Batch of 20210716A:** **Width:** For S: 79~83mm For M: 93~97mm	Passed

Application - Physical Dimensions Test		**Length:** For S: ≥220mm For M: ≥230mm For L: ≥230mm For XL: ≥230mm	For L: 101-105mm For XL: 110mm **Length:** For S: 233~237mm For M: 233~237mm For L: 240~244mm For XL: 240~244mm Lot Batch of 20210719A: **Width:** For S: 79~83mm For M: 94~97mm For L: 101-104mm For XL: 110mm **Length:** For S: 234~236mm For M: 234~237mm For L: 240~244mm For XL: 240~245mm **Lot Batch of 20210721C:** **Width:** For S: 80~85mm For M: 94~98mm For L: 105-109mm For XL: 110mm **Length:** For S: 230~235mm For M: 235~238mm For L: 239~243mm For XL: 240~243mm	
		Thickness: Finger: ≥0.05mm Palm: ≥0.05mm	**Lot Batch of 20210716A:** For S/M/L/XL:	

			Finger min: 0.12mm Palm min: 0.08mm **Lot Batch of 20210719A:** For S/M/L/XL: Finger min: 0.13mm Palm min: 0.08mm **Lot Batch of 20210721C:** For S/M/L/XL: Finger min: 0.13mm Palm min: 0.08mm	
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Dimensions Test	To determine the tensile strength and ultimate elongation before and after acceleration aging	**Before Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥500% **After Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥400%	**For all three lots:** **Before Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥500% **After Aging:** Tensile Strength: ≥14Mpa Ultimate Elongation: ≥400%	Passed
ASTM D6319-19 (ASTM D5151-11) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	**For all three lots:** Pass at AQL 2.5	Passed
ASMT D6319-19 (ASTM D6124-11) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	< 2.0 mg/glove	**Lot Batch of 20210716A:** For S/M/L/XL: Pass at 0.12 mg/glove **Lot Batch of**	Passed

			20210719A: For S/M/L/XL: Pass at 0.15 mg/glove **Lot Batch of 20210721C:** For S/M/L/XL: Pass at 0.21 mg/glove	

2) Biocompatibility Testing Summary:

Test Method	Test Purpose	Acceptance Criteria	Test Results	Conclusion
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin irritation and skin sensitization	To evaluate the potential intracutaneous reactivity caused by intracutaneously inject the extract to rabbits	Under the conditions of study not an irritation	Under the conditions of study not an irritation	Passed
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin irritation and skin sensitization	To determine the skin sensitization potential in guinea pigs.	Under the conditions of the study not a sensitization	Under the conditions of the study not a sensitization	Passed
ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for acute systemic toxicity	The test item was evaluated for acute systemic toxicity in ICR mouse	Under the conditions of the study no systemic toxicity	Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	Passed

8.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

9. Final Conclusion:

The subject device is a safe, as effective, and perform as well as or better than the legally marketed predicated K203593.