March 9, 2022

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

Re: K213851
Trade/Device Name: Disposable Medical Nitrile gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: December 6, 2021
Received: December 10, 2021

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,

For Clarence W. Murray, III, Ph.D.
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)*
K213851

Device Name
Disposable Medical Nitrile gloves

Indications for Use *(Describe)*
The Disposable Medical Nitrile gloves 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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K213851 510(k) Summary

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: December 6, 2021

2. Submitter's Information

Sponsor Name: Guangdong Xingcan Brothers Medical Technology Co.,Ltd
Address: Room B10, 4th Floor, No. 137 (plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou
Establishment Registration Number: Applying
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Company: Share Info (Guangzhou) Medical Consultant Ltd.
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: Disposable Medical Nitrile gloves
Specifications: Small (S), Medium (M), Large (L), X-large (XL)
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 proposed devices are powder-free nitrile examination gloves, provided as non-sterile and disposable devices. The proposed devices are mainly made from nitrile and there are four sizes, including small (S), medium (M), large (L), X-large (XL) for optional. The gloves are composed of Butadiene-Acrylonitrile Copolymers (CAS No.9003-18-3) and blue colorant Pigment Blue (CAS No.147-14-8). The examination glove is a smooth surface and a rolled rim at the cuff edge.
The Medical nitrile examination gloves meet the specifications in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

6. Intended Use / Indications for Use

The Disposable Medical Nitrile gloves 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. Technological Characteristics Comparison

Elements of Comparison	Subject Device	Predicate Device	Result
Company	Guangdong Xingcan Brothers Medical Technology Co.,Ltd	Guang Dong Kingfa SCI. & TECH.CO., LTD.	--
510 (k) Number	K213851	K203593	--
Trade Name	Disposable Medical Nitrile gloves	Patient Examination Gloves	--
Product Code	LZA	LZA	Same
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

Elements of Comparison	Subject Device	Predicate Device	Result
Indications For Use	The Disposable Medical Nitrile gloves 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.	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-use, powder-free, non-sterile device.	Same
Material of Use	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
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:**	Meets requirements of the ASTM D6319-19 **After Aging:**	

Elements of Comparison	Subject Device	Predicate Device	Result
	Tensile Strength: ≥14Mpa Ultimate Elongation: ≥400%	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
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

8. Test Summary

2.1 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 Application – Physical Dimensions Test	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 **Length:** For S: ≥220mm For M: ≥230mm For L: ≥230mm For XL: ≥230mm	**For Lot 20210825B:** **Width:** For S: 83~86mm For M: 91~92mm For L: 104-106mm For XL: 112-114mm **Length:** For S: 234~236mm For M: 235~237mm For L: 237~239mm For XL: 237~239mm **For Lot 20210827A:** **Width:** For S: 83~85mm For M: 91~93mm For L: 104-106mm For XL: 111-113mm **Length:** For S: 234~236mm For M: 235~237mm For L: 237~239mm For XL: 237~239mm **For Lot 20210830A:** **Width:** For S: 83~85mm For M: 90~92mm For L: 104-106mm For XL: 112-115mm **Length:** For S: 234~236mm	Passed

			For M: 235~237mm For L: 237~240mm For XL: 237~239mm	
		Thickness: Finger: ≥0.05mm Palm: ≥0.05mm	**For Lot 20210825B:** **Finger:** For S/M: Pass at 0.11mm For L/XL: Pass at 0.12mm **Palm:** For S/M/L/XL: Pass at 0.08mm **For Lot 20210827A:** **Finger:** For S: Pass at 0.11mm For M/L/XL: Pass at 0.12mm **Palm:** For S/M/L/XL: Pass at 0.08mm **For Lot 20210830A:** For S/M/L: Pass at 0.11mm For XL: Pass at 0.12mm **Palm:** For S/M/L/XL: Pass at 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	**For Lot 20210825B:** For S/M/L/XL: Pass at 0.22 mg/glove **For Lot 20210827A:** For S/M/L/XL: Pass at 0.19 mg/glove **For Lot 20210830A:** For S/M/L/XL: Pass at 0.20 mg/glove	Passed

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	To evaluate the potential intracutaneous reactivity caused by	Under the conditions of study not an irritation	Under the conditions of study not an irritation	Passed

skin irritation and skin sensitization	intracutaneously inject the extract to rabbits			
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

2.1 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 K203191.