September 21, 2021

Foshan Kangkang Biotechnology Co., LTD
Yico Xie
General Manager
2nd Floor, Building 4, Dongfang Industrial Park, Xiaotang
Industrial Avenue, Shishan Town, Nanhai District
Foshan City, Guangdong 528225
China

Re: K211073
Trade/Device Name: Disposable Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 4, 2021
Received: August 4, 2021

Dear Yico Xie:

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, PhD
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)*
K211073

Device Name
Disposable Nitrile Examination Gloves

Indications for Use *(Describe)*
Disposable Nitrile Examination Gloves is a non-sterile disposable device intended for medical purposes that is worn on the examiner's 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

K211073

Date of Summary Preparation: March 31, 2021
Date of Modification: July 23, 2021

1. Submitter's Identifications

Submitter's Name: FOSHAN KANGKANG BIOTECHNOLOGY CO., LTD
Address: 2nd Floor，Building 4，Dongfang Industrial Park, Xiaotang Industrial Avenue, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China
Contact Person: Yico Xie
Contact Title: General Manager
Contact E-mail Address: kangkang_biotechnology@aliyun.com
Zip code: 528225
Telephone: +86-13702554142

2. Correspondent's Identifications

Correspondent's Name: FOSHAN KANGKANG BIOTECHNOLOGY CO., LTD
Address: 2nd Floor, Building 4, Dongfang Industrial Park, Xiaotang Industrial Avenue, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China
ZIP Code: 528225
Contact Person: Yico Xie
Contact Title: General Manager
Contact E-mail Address: Kangkangfda@126.com
Telephone: +86-13702554142

3. Name of the Device

Device Classification Name: Non-powdered Patient examination glove
Common Name: Polymer Patient Examination Glove
Trade Name: Disposable Nitrile Examination Gloves
Model/Size: S, M, L, XL
Classification Panel: General Hospital
Product Code: LZA
Device Classification: Class I

4. The Predicate Devices

K181106 Powder Free Nitrile Patient Examination Gloves, Blue Color

5. Device Description

The proposed device is Powder Free Nitrile Examination Gloves. The proposed device is blue. The proposed device is non-sterile.

6. Indications for Use

Disposable Nitrile Examination Gloves is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

7. Summary of Technological Characteristics

Table 1 Comparison to Predicate Device

	Proposed Device		Primary predicate device		Comparison
510k Number	K211073		K181106		
Manufacturer	FOSHAN KANGKANG BIOTECHNOLOGY CO., LTD		JiangSu DongXin Medical Technology Co., Ltd		
Proprietary Name	Disposable Nitrile Examination Gloves		Powder Free Nitrile Patient Examination Gloves, Blue Color		
Regulation Number	21 CFR 880.6250		21 CFR 880.6250		Same
Product Code	LZA		LZA		Same
Color	Blue		Blue		Same
Size	S, M, L, XL		S, M, L, XL		Same
Indications for Use	Disposable Nitrile Examination Gloves is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.		Powder Free Nitrile Patient Examination Gloves, Blue Color 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.		Same
Device Description and Specifications	Meets ASTM D6319-19		Meets ASTM D6319-10		Same
Freedom from Pinholes IL I AQL2.5	1) Inspection 125pcs, Inspection Level I AQL2.5, and Accept/Reject criteria of 7/8 2) Water leakage test: 0 noncompliance.		1) Inspection Level I AQL2.5, and Accept/Reject criteria of 10/11 2) Water leakage test: 5 noncompliance is allowed.		Similar
Dimensions –Length ILS-2 AQL4.0	Meets ASTM D6319-19 230mm min. for all sizes		232 mm min for all sizes		Similar
Dimensions –Width IL S-2 AQL4.0	Meets ASTM D6319-19				Similar
	S	82-85mm	S	76-90mm	
	M	93-97mm	M	89-102mm	
	L	100-103mm	L	108-119mm	
	XL	110-111mm	XL	115-128mm	
Dimensions –Thickness IL S-2 AQL4.0	Meets ASTM D6319-19 Thickness (mm) min. Finger: 0.13		Thickness (mm) min. Finger: 0.08 Palm: 0.08		Similar

	Palm: 0.07				
Physical Properties IL S-2 AQL4.0	Before Aging	After Aging	Before Aging	After Aging	Similar
Tensile Strength (MPa)	15.3-23.4	14.1-30.6	18-25	17-22	
Ultimate Elongation (%)	500.972-595.086	416.106-601.187	550-600	450-570	
Residual Powder	1) Checked on 5pcs sub-samples (N=5). 2) Result as following: Mean: 0.18mg/glove		2) Checked on 5pcs sub-samples (N=5). 2) Result as following: Mean: 0.1mg/pcs		Similar
Materials	Nitrile		Nitrile		Same
Single Patient Use	Single Patient Use		Single Patient Use		Same
Biocompatibility	Under the conditions of this study, the test article was a non irritant or non sensitizer		Under the conditions of this study, the test article was a non irritant or non sensitizer		Same
	Under the conditions of this study, the test article was slight cytotoxic to L-929 cells and was accepted in the agar diffusion method.		Under the conditions of this study, the test article was non cytotoxicity to L-929 cells.		Similar
	Under the conditions of this study, the test article was showed no evidence of causing acute system toxicity in the ICR mice.		Not publicly available		Different[7]
Labeling for the legally marketed device to which substantial equivalence is claimed	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile		-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile		Same
Standard	ASTM D6319-19 ASTM D6124-06 (Reapproved 2017) ASTM D5151-19 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017		ASTM D6319-10(Reapproved 2015) ASTM D6124-06 (Reapproved 2017) ASTM D5151-06(Reapproved2015) ISO 10993-5:2009 ISO 10993-10:2010		Similar[8]

8. Summary of Non-Clinical Testing:

Non-clinical tests were conducted to verify that the proposed device met acceptance criteria

for each test.
ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
ISO10993-11:2017 Biological evaluation of medical devices - Part11: Tests for systemic toxicity, implemented test for acute system toxicity
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
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

Summary of the non-clinical testing is shown as below:

Test Methodology	Purpose	Acceptance Criteria	Results
In Vitro Cytotoxicity Test: Agar diffusion Method	The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.	The test sample met the requirements of the test if the biological response was less than or equal to grade 2.	Under the conditions of this study, the test article was Slight cytotoxic and was accepted in the agar diffusion method.
Skin Sensitization Test: Guinea Pig Maximization	The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.	Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals. If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Skin Irritation Test: Extraction Method	To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.	When blank or negative control was used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.	The test result showed that the response of the test article extract was categorized as negligible under the test condition.
Acute Systemic Toxicity Test: Extraction Method	The test was designed to evaluate the potential acute system toxicity caused by test article contact with the ICR mice and extrapolating the results to humans.	Within the monitoring period (72 h), if the toxicosis response of testing group is not greater than that of control group, the testing sample is regarded as acceptable. In case that two or more mice show the medium toxicosis symptom or die, the testing sample is regarded as unacceptable. If any animals treated with the sample show only slight signs of biological reactivity, and not more than one animal shows gross symptoms of biological reactivity or dies, repeat the testing using groups of 10 animals. On the repeat test, if all 10 animals treated with the sample show no scientifically meaningful biological reactivity above the vehicle control animals during the observation period, the sample meets the requirements of this test.	The test article showed no evidence of causing acute system toxicity in the ICR mice.

<table>
<tr>
<td>Watertightness Test for Detection of Holes:
Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (ISO 2859-1:1999)
Standard Specification for Nitrile Examination Gloves for Medical Application (ASTM D6319 - 19)
Standard Test Method for Detection of Holes in Medical Gloves (ASTM D 5151-19)</td>
<td rowspan="3">The test was designed to validate the properties of the test glove.
Water tightness test for detection of holes, physical dimensions and physical properties were performed on the test glove to test its properties.
The results showed each property of the test glove was acceptable under this test condition.</td>
<td>Items: Water lack,
Batch size: 35000
Inspectional level: I
AQL: 2.5
Sample Demand: 125
Criterion: ⩽7</td>
<td>Number of Conforming: 125 Glove
Number of Non-confirming: 0 Glove</td>
</tr>
<tr>
<td>Physical Dimensions Test:
Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (ISO 2859-1:1999)
Standard Specification for Nitrile Examination Gloves for Medical Application (ASTM D6319 - 19)
Standard Practice for Rubber—Measurement of Dimensions (ASTM D 3767-03(2014))</td>
<td>Items: Physical dimension test
Batch size: 35000
Inspectional Level: S-2
AQL: 4.0
Sample Demand: 13</td>
<td>The test result was considered to be acceptable.</td>
</tr>
<tr>
<td>Determination of Physical Properties:
Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL)</td>
<td>
<table>
<tr><td rowspan="2">Items</td><td colspan="2">Before Aging</td><td colspan="2">After Accelerated Aging</td></tr>
<tr><td>Tensile Strength</td><td>Ultimate Elongation</td><td>Tensile Strength</td><td>Ultimate Elongation</td></tr>
<tr><td>Physical Requirements</td><td>≥14MPa</td><td>≥500%</td><td>≥14MPa</td><td>≥400%</td></tr>
</table>
</td>
<td>The test result was considered to be acceptable.</td>
</tr>
</table>

<table>
<tr>
<td>for lot-by-lot inspection (ISO 2859-1:1999)
Standard Specification for Nitrile Examination Gloves for Medical Application (ASTM D6319 - 19)
Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension (ASTM D 412-06a(2013))</td>
<td></td>
<td>
<table>
<tr><td>Inspection Level</td><td colspan="4">S-2</td></tr>
<tr><td>AQL</td><td colspan="4">4.0</td></tr>
<tr><td>Sample Size Code Letter</td><td colspan="4">E</td></tr>
<tr><td>Batch Size</td><td colspan="4">35000</td></tr>
<tr><td>Sample Demand</td><td colspan="4">13</td></tr>
<tr><td>Number of Non-conforming</td><td>≤1</td><td>≤1</td><td>≤1</td><td>≤1</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>Surface Powder Test of "powder-free" gloves:
Standard Specification for Nitrile Examination Gloves for Medical Application (ASTM D6319 - 19)
Standard Test Method for Rubber—Deterioration in an Air Oven (ASTM D 573-04(2015))
Medical gloves - Determination of removable surface powder ISO 21171-2006
Standard Test Method for Residual Powder on Medical Gloves ASTM D6124 - 06(2017)</td>
<td></td>
<td>Powder-free Synthetic Exam
3 sets of 2 gloves/batch, Average: 0.63mg/glove</td>
<td>Analyte: Residual Powder
Result: 0.18mg/glove
The results showed each property of the test glove was acceptable under this test condition.</td>
</tr>
</table>

9. Clinical Test Conclusion

Clinical testing is not needed for this device.

10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.