May 8, 2023

Holik Asia Group Co., Ltd
℅ Libray Chang
Official Correspondent
Shanghai Spica Management Consulting Co., Ltd.
609 Room, No.133 Shengang Avenue, Pudong New District
Shanghai, 201306
China

Re: K223280
Trade/Device Name: Disposable nitrile gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 12, 2023
Received: April 12, 2023

Dear Libray Chang:

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
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)*
K223280

Device Name
Disposable nitrile gloves

Indications for Use *(Describe)*
The Disposable nitrile gloves are 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.

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510(K) Summary

K223280

Type of submission	Traditional
Date prepared	April 12, 2023

Submission sponsor

Manufacturer Name	HOLIK ASIA GROUP CO.,LTD
Address	NO.18 Nanyi Road, Xuanzhou Economic Development Zone, Liqiao Town, Xuanzhou District, Xuancheng City, Anhui Province, China
Tel	86-13585161180
Email	monica@holikasia.com
Contact Person	Monica Zhou

Device identification

Trade Name	Disposable nitrile gloves
Regulation Number	21 CFR 880.6250
Regulation Name	Non-Powdered Patient Examination Glove
Device Classification	Class I
Product Code	LZA
Panel	General Hospital

Application correspondent

Company Name	Shanghai Spica Management Consulting Co., Ltd.
Address	609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China
Tel	86-13020102321
Email	Libray@spicagloble.com

510(K) Summary

Contact Person	Libray Chang

Predicate device information

Sponsor	Shanxi Nacosa Medical Technology Co.,Ltd
Trade/Device Name	Nitrile Examination Gloves
510(K) number	K212924
Regulation Number	21 CFR 880.6250

Indications for use

The Disposable nitrile gloves are 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.

Device description

The Disposable nitrile gloves are powder free nitrile examination gloves. The Disposable nitrile gloves will be provided in blue. It can be available in four specifications: S,M,L and XL. And it is non-sterile.

Performance Testing - Clinical

Not Applicable.

Performance Testing - Animal

Not Applicable.

Technological Characteristic Comparison

Provided below is a comparison of the subject device with the predicate device.

Table 6A: General Comparison

Item	**Subject Device K223280**	**Predicate Device** (K212194)	**Comparison**
Product Code	LZA	LZA	Same
Regulation No.	21 CFR 888.6250	21 CFR 888.6250	Same
Class	I	I	Same
Intended Use	The Disposable nitrile gloves are 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	Nitrile	Nitrile	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Colorant	Blue	Blue	Same
Labeling	Single-use indication, powder free, device color,	Single-use indication, powder free, device color,	Same

Information		device name,glove size and quantity, Non-Sterile		device name, glove size and quantity, Non-Sterile		
Dimensions(mm)		Length(mm): ＞230; Width(mm): S: 85±5mm M: 95±5mm L: 105±5mm XL: 115±5mm Meet the requirements of ASTM D6319-19		Length(mm): ＞230; Width(mm): S: Average 84mm M: Average 95mm L: Average 111mm XL: Average 115mm Meet the requirements of ASTM D6319-19		Similar
Thickness(mm)		Finger: 0.09-0.15 Palm: 0.06-0.07		Finger: 0.12-0.15 Palm: 0.08-0.10		Similar
Physical Properties	Before Aging	Tensile Strength	≥14MPa	Tensile Strength	17-38 MPa	Similar
		Ultimate Elongation	≥500%	Ultimate Elongation	501-565%	Similar
	After Aging	Tensile Strength	≥14MPa	Tensile Strength	18-43MPa	Similar
		Ultimate Elongation	≥400%	Ultimate Elongation	500-564%	Similar
Freedom from Holes		Be free from holes when tested in accordance with ASTMD5151		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5		Similar
Powder Content		＜0.1mg Meet the requirements of ASTM D6124 ＜2.0 mg/gloves		0.1-0.3mg Meet the requirements of ASTM D6124 ＜2.0 mg/gloves		Similar
Biocompatibility		ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer.		ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer.		Same
		ISO 10993-11; Under the condition of acute systemic toxicity test, the test article did not show acute systemic		ISO 10993-11; Under the condition of acute systemic toxicity test, the test article did not show acute systemic		Same

	toxicity in vivo.	toxicity in vivo.	
	ISO 10993-5 Under conditions of the study, device extract is cytotoxic.	ISO 10993-5 Under conditions of the study, device extract is cytotoxic.	Same

Analysis:
The physical dimensions, physical properties and powder content are different with that of the predicate, but they all meet the requirements of ASTM D6319.

Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves.

Table 6B: Summary of Non-clinical performance testing

Test method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length(mm): ＞230; Width(mm):	Length(mm): ＞230/Pass; Width(mm):

		S: 85±5mm M: 95±5mm L: 105±5mm XL: 115±5mm			S: 85mm/Pass M: 95mm/Pass L: 105mm /Pass XL: 115mm/Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05			Thickness (mm): Finger: 0.09-0.15/Pass Palm: 0.06-0.07/Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			＜0.1mg/Pass
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	Pass
			Ultimate Elongation	≥500%	
		After Aging	Tensile Strength	≥14MPa	
			Ultimate Elongation	≥400%	
ISO 10993-5	Cytotoxicity	No cytotoxic			Fail
ISO 10993-11	Acute Systemic Toxicity	Non- acute systemic toxicity			Pass
ISO 10993-10	Irritation	Non-irritating			Pass
ISO 10993-10	Sensitization	Non-sensitizing			Pass

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Disposable nitrile gloves are as safe, as effective, and performs as well as or better than the legally marketed predicated device K212924.