December 18, 2021

USA Gloves
Zishan Momin
Chief Operating Office
12505 Reed Rd Ste 110
Sugar Land, Texas 77478

Re: K211624
Trade/Device Name: USA Gloves Nitrile Powder Free Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 16, 2021
Received: November 16, 2021

Dear Zishan Momin:

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)*
K211624

Device Name
USA Gloves Nitrile Powder Free Exam Gloves

Indications for Use *(Describe)*
Intended for medical purpose that are worn on the examiner's hand 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

May 16, 2021

Zishan Momin
Tel: (281) 827-3691
Email: sharez@usagloves.com

510(K) Summary – K211624

Submitter Information

FDA 510(K) K211624	
Product/Trade Name	USA Gloves Nitrile Powder Free Exam Gloves
510(K)	K211624
Applicant Name:	Glove Ventures LLC dba USA Gloves
Applicant Address (city, state, zip):	Stafford, TX 77477
Applicant Contact Person:	Zishan Momin
Correspondent Name:	Zishan Momin
Correspondent Address (full address):	12505 Reed Rd Ste 110 Sugar Land, TX 77478 USA
Correspondent Contact Person:	Zishan Momin
Correspondent Contact Phone#:	
Correspondent Contact Email:	zishan@usagloves.com

Predicate Devices

The USA Gloves Nitrile Powder Free Exam Gloves is identical to the Hi-Care Thai Gloves Co. Ltd. Blue Nitrile Examination Gloves Powder free which is the subject of a clearance letter from the Agency under 510(k) number K202384, which itself, was predicated on the subject of K192333. The predicate Hi-Care Thai Gloves Co. Ltd. Blue Nitrile Examination Gloves Powder free and USA Gloves Global Nitrile Gloves are the same in design and use.

Indications for Use:
USA Gloves Nitrile Powder Free Exam Gloves is intended as a powder-free patient examination glove and 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. The USA Gloves Nitrile Powder Free Exam Gloves is a single use, disposable device, provided non-sterile.

Device Description:
USA Gloves Nitrile Gloves and aforementioned predicate device are Non-powdered patient examination glove, as defined in 21 CFR 880.6250.

Former Release Powder or Chemical: No release powder or chemical is used.

USA Gloves Nitrile Gloves is not intended to be sterilized. The device is delivered in packaging which may be used as a protective carrying case.

Technological Characteristics Comparison Table

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
		Subject	Predict	
510(K) Number		**K211624**	**K202384**	----
Name of device		USA Gloves Nitrile Powder Free Exam Glove	Blue Nitrile Examination Gloves Powder free	----
Product Code		LZA	LZA	----
Dimensions	ASTMD 6319-10 (Reapproved 2015)	Length Min 230 m Width Min 95+/-10mm (for medium size)	Length Min 230 mm Width Min 95+/mm (for medium size)	Same
Physical Properties	ASTMD 6319-10 (Reapproved 2015)	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	Same
Thickness	ASTMD 6319-10 (Reapproved 2015)	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
Powder Residue	ASTMD 6319-10	≤2 mg/glove	≤2 mg/glove	Same
	Primary Skin Irritation- ISO 10993-10:2010(E)	Under the condition of study not an irritant	Under the condition of study not an irritant	Same

Table1: USA Gloves Nitrile Gloves / the Hi-Care Thai Gloves Co. Ltd. Blue Nitrile Examination Gloves Powder Free Comparison

Summary of Nonclinical Testing

Provided below is a summary of the standards and test methodology that was used to evaluate and demonstrate that the subject device met the performance specification and acceptance criteria for a nitrile glove.

Test Methodology	Purpose	Acceptance Criteria	Results
ASTMD 6319-10 (Reapproved 2015)	Physical Properties	Before Aging Tensile Strength min 14 Mpa Ultimate Elongation Min 500% After Aging Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	Pass
ASTMD 6319-10 (Reapproved 2015)	Dimensions	Length Min 230 m Width Min 95+/-10mm (for medium size)	Pass
ASTMD 6319-10 (Reapproved 2015	Thickness	Palm min 0.05 mm Finger min 0.05 mm	Pass
ASTMD 6319-10 (Reapproved 2015	Powder Residue	≤2 mg/glove	Pass
ISO 10993-5	Biocompatibility-Cytotoxicity	No Cytotoxicity	Pass
ISO 10993-10	Skin Irritation	No Skin Irritation	Pass
ISO 10993-11	Acute Systemic Toxicity	No Systemic Toxicity	Pass

Conclusion

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