September 24, 2022

Dainam Glove Joint Stock Company
% Jenny Nguyen
Office Manager
Bayneto LLC
13480 Veterans Memorial Drive, Suite F
Houston, Texas 77014

Re: K212751
Trade/Device Name: Powder Free Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 16, 2022
Received: August 18, 2022

Dear Jenny Nguyen:

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.
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)*
K212751

Device Name
Powder Free Nitrile Examination Glove

Indications for Use *(Describe)*
Blue Nitrile Examination Gloves Powder Free is disposable devices 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.

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510(k) Summary - K212751

Submitted by:	Dai Nam JSC. 1765A Thu Dau Mot Hiep An Ward, Thu Dau Mot, Vietnam.
Contact Person:	Damon Nguyen Director of U.S. Market dqn1967@gmail.com
Telephone Number:	832-458-4388
Date submitted:	September 20, 2022
Trade/Device Name:	Powder Free Nitrile Examination Glove
Regulation Number:	21 CFR 880.6250
Regulation Name:	Non-powdered Patient Examination Glove
Regulatory Class:	Class I
Product Code:	LZA

Identification of the legally marketed device:

Predicate Device Name: ***Powder Free Black Nitrile Examination Glove***
Predicate 510(K) Number: ***K201428***
Manufacturer's Name: ***VIETGLOVE CORPORATION***

5.1 Product Description

Dainam JSC., Powder Free Gloves are Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR880.6250). The gloves are made from acrylonitrile- butadiene copolymer dispersion. These gloves are blue in color and are powder free, non-sterile, single use and disposable and available in size XS-extra small, S-small, M-medium, L-Large, XL- Extra-large.

5.2 Intended Use/Indications for Use

Blue Nitrile Examination Gloves Powder Free are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.

5.3 Comparison of Technological Characteristics

Product	**K201428** **(Predicate)**	**K212751** **(Subject)**	**Results**
Design and Size Availability	S,M,L	XS,S,M,L,XL	Similar
Materials	Nitrile (Acrylonitrile butadiene)	Nitrile (Acrylonitrile butadiene)	Same
Intended use/Indication for Use	Non-Powdered Patient Examination Glove are disposable gloves used during medical examinations and procedures to help prevent cross-contamination between caregivers and patients	Blue Nitrile Examination Gloves Powder Free are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Similar
Color	Black	Blue	…
Product Code	LZA	LZA	Same
Classification	Class 1	Class 1	Same
510(K) Number	**K201428**	**K212751**	**…**

Characteristics	**Standards**	**Device Performance**		**Comparison**
		Predicate	**Subject**	
510(K) Number		K201428	K212751	----
Name of device		Powder Free Black Nitrile Examination Glove	Powder Free Nitrile Examination Glove	----
Dimensions	ASTM D6319-2019	Length Min 242 m Width Min 95+/-10 mm (for medium size)	Length Min 230 mm Width Min 95+/-10 mm (for medium size)	Similar

Characteristics	Standards	Device Performance		Comparison
		Predicate	Subject	
Physical Properties	ASTM D6319-2019	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 508%	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 505%	Similar
Thickness	ASTM D6319-2019	Palm min 0.06 mm Finger min 0.11 mm	Palm min 0.06 mm Finger min 0.09 mm	Similar
Powder Residue	ASTM D6319-2019	S: 0.43mg/glove M: 0.31 mg/glove L: 0.47 mg/glove	XS: 0.3mg/glove S: 1.4mg/glove M: 2.0 mg/glove L: 0.5 mg/glove XL: 0.7mg/glove	Similar
Biocompatibility	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
	Dermal Sensitization- ISO 10993-10:2010(E)	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
	In vitro cytotoxicity ISO10993-5 :2009(E)	Under the conditions of the study, cytotoxic	Under the conditions of the study cytotoxic	Same
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	Under the conditions of study the device extracts do not pose a systemic toxicity concern	Under the conditions of study the device extracts do not pose a systemic toxicity concern	Same
	Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	N/A	Under the conditions of the study the device extract did not show a material mediated pyrogenicity response.	Different
Watertight (1000 ml)	ASTM D5151- 2019	Passes AQL-2.5	Passes AQL-2.5	Similar
Material	ASTM D6319- 2019	Nitrile	Nitrile	Same
Color	-	Black	Blue	Different
Texture	-	Finger Texture	Finger texture	Same
Size	ASTM D6319- 2019	Small, Medium, Large	Extra Small, Small, Medium, Large, Extra Large	Similar
Sterility		Non-sterile	Non-sterile	Same

Characteristics	Standards	Device Performance		Comparison
		Predicate	Subject	
Single Use	Medical Glove Guidance Manual	Single Use	Single Use	Same
Manufacturer(s)	-	Vietglove Corporation	DaiNam Glove JSC	------

5.4 Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device complies with the following standards:

1) ISO 10993-10:2009 MTT Method MEM with 10%FBS extract: In Vitro Cytotoxicity Test of NITRILE EXAM GLOVES.
2) ISO 10993-10:2010 Guinea Pig Maximization Test 0.9% sodium Chloride Injection Extract: Sensitization Test of NITRILE EXAM GLOVES.
3) ISO 10993-10:2010 0.9% sodium Chloride Injection Extract: Skin Irritation Test of NITRILE EXAM GLOVES.
4) ISO 10993-10:2010 Guinea Pig Maximization Test Sesame Oil Extract: Sensitization Test of NITRILE EXAM GLOVES.
5) ISO 10993-10:2010 Sesame Oil Extract: Skin Irritation Test of NITRILE EXAM GLOVES.
6) ISO 10993-11:2017 Intravenous 0.9% Sodium Chloride Injection Extract: Acute Systemic Toxicity Test of NITRILE EXAM GLOVES.
7) ISO 10993-11:2017 Intravenous Sesame Oil Extract: Acute Systemic Toxicity Test of NITRILE EXAM GLOVES
8) ISO 10993-11:2017 0.9% Sodium Chloride Injection Extract Rabbit: Pyrogen Test of NITRILE EXAM GLOVES
9) ASTM D6319-19, Standard Specification for Gloves for Medical Application.

Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-2019 Standard Specification for Gloves for Medical Application	To determine the length of the gloves	Min 230 mm for all sizes	X-Small: +/-240 mm Small: +/-240 mm Medium: +/-240 mm Large: +/-240 mm X-Large: +/-240 mm
ASTM D6319-2019 Standard Specification for Gloves for Medical Application	To determine the width of the gloves	X-Small: 70+/-10 mm Small: 80+/-10 mm Medium: 95+/-10mm Large: 110+/-10 mm X-Large: 120+/-10 mm	X-Small: 70+/-10 mm Small: 80+/-10 mm Medium: 95+/-10mm Large: 110+/-10 mm X-Large: 120+/-10 mm
ASTM D6319-2019 Standard Specification for Gloves for Medical Application	To determine the Thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	Size / Palm / Finger X-Small 0.07mm 0.10mm Small 0.07mm 0.9mm Medium 0.07mm 0.9mm Large 0.07mm 0.8mm X-Large 0.07mm 0.7mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D6319-2019 Standard Specification for Gloves for Medical Application	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 14Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all sizes	**Size** X-Small Small Medium Large X-Large	**Before ageing** 27Mpa 26Mpa 25Mpa 33Mpa 32Mpa	**After ageing** 25Mpa 26Mpa 27Mpa 36Mpa 33Mpa
	To Determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 500% Min for all sizes **After Ageing** Ultimate Elongation 400% Min for all sizes	 X-Small Small Medium Large X-Large	**Before ageing** 520% 567% 553% 568% 539%	**After ageing** 509% 545% 538% 560% 570%

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D5151-2019 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 2.5	
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 Mg/Glove Max	**Size** X-small Small Medium Large X-Large	**Residual Powder Content** 0.3mg/glove 1.4mg/glove 2 mg/glove 0.5 mg/glove 0.7mg/glove

5.5 BIOCOMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done for irritation.	To determine the potential of the glove under test to produce dermal irritation in Rabbits	Under the condition of study not an irritant	Under the condition of study not an irritant
ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done Skin sensitization.	To determine the skin sensitization potential of the glove in Guinea Pig.	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer
ISO 10993-5:2009 biological evaluation of medical devices - part 5, tests for in vitro cytotoxicity.	To evaluate the in vitro cytotoxic potential of the test item in L-929 mouse fibroblasts cells using elution method.	Under the conditions of study non cytotoxic	Under the conditions of the study cytotoxic.
ISO 10993-11:2017 biological evaluation of medical devices - part 11, tests for systemic toxicity.	To determine the acute systemic toxicity potential of the test item extracts in mice.	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	Under the conditions of study the device extracts do not pose a systemic toxicity concern
Material Mediated Pyrogenicity ISO 10993- 11:2017	To determine the pyrogenic potential of the test item extract following intravenous injection in Rabbits.	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.

5.6 Summary of Clinical Testing

Not applicable - Clinical data is not needed for the subject gloves.

5.7 Conclusion

The conclusions drawn from the non-clinical test demonstrate that the subject device is as safe as effective and performs as well as or better than the legally marketed predicated device.