June 16, 2021

Megine Industries Sdn Bhd
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K211310
Trade/Device Name: AMADEX - Nitrile Powder Free Examination Gloves Non-Sterile (Blue, Black, Orange)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: June 11, 2021
Received: June 14, 2021

Dear Prithul Bom:

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,

Ryan Ortega, PhD
Acting 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)*
K211310

Device Name
AMADEX - Nitrile Powder Free Examination Gloves Non-Sterile, (Blue, Black, Orange)

Indications for Use *(Describe)*
The powder-free patient examination glove 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.

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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MEGINE INDUSTRIES SDN BHD

510 (K) SUMMARY

This summary of 510(K) is being submitted in Accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 **(K)** number is: K211310

I. APPLICANT INFORMATION:

510 (K) Owner's Name	MEGINE INDUSTRIES SDN BHD
Address	B-05-02, The Vertical Business Suites, 8, Jalan Kerinchi, Bangsar South, 59200 Kuala Lumpur, Malaysia
Phone	+60328566180
Fax	+60328566180
E-mail	benjamin.ng@meginegroup.com.my
Contact Person	Benjamin Ng Soong Jing
Designation	Managing Director
Contact Number	+60328566180
Contact Email	benjamin.ng@rneginegroup.com.my
Date Submission	28th April 2021

2. DEVICE IDENTIFICATION:

Name of the Device	AMADEX - Nit1ile Powder Free Examination Gloves Non-Sterile, (Blue, Black, Orange)
Product Proprietary or Trade Name	AMADEX
Common or Usual Name	Examination Gloves
Classification Name	Patient Examination Glove
Device Classification	Class - I
Product Code	LZA
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

3. PREDICATE DEVICE INFORMATION:

Predicate Device	Nitrite Examination Powder Free Glove, Black, Nitrile Examination Powder Free Glove, Orange.
510 (K) Number	K172867
Regulatory Class	I
Product Code	LZA

4. DEVICE DESCRIPTION:

AMADEX - Nitrile Powder Free Examination Gloves Non-Sterile, (Blue, Black, Orange) are Class I patient examination gloves bearing the product code Nitril e - LZA (2 ICFR880.6250). AMADEX - Nitrile Powder Free Examination Gloves Non-Sterile,(Blue, Black, Orange) meet all the requirements of ASTM standard D 6319-10 and FDA 21 CFR 880.6250. The AMADEX - Nitrile Powder Free Examination Gloves Non-Sterile, (Blue, Black, Orange) is sing le-use device to prevent contamination between patient and examiner.

5. INDICATION OF USE:

The powder-free patient examination glove 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.

6. TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

Characteristics	Standards	Device Performance		Remark s
		Predicate	Subject	
5 10 (K) number		K172867	(Kxxxxxx)	-
Name of Device		Nitrile Examination Powder Free Glove, Blac k, Nitrile Examination Powder Free Glove, Orange.	AMADEX- Nitrile Powder Free Examination Gloves Non-Sterile,(Blue, Black, Orange)	-
Dimension s	ASTM D 6319-10 Length: Range - Length: Min -240 mm (All Size s)	Res ult: Length h: Min 240mm By Sizes:	Result: Length: Min 240mm By Sizes:	Sam e

	Width: Range value - **XS** : Length : 220mm, Width: 70 ± 10 mm S : Length : 220mm, Width: 80 ± 10 mm **M** : Length : 230mm, Width: 95 ± 10 mm L : Length : 230mm, Width: 110 ± JO mm XL : Length : 230mm, Width: 120 ± 10 mm	**XS-** Width: 76 ± 3 mm **S -** Width: 84 ± 3 mm **M-** Width: 94 ± 3 mm L - Width: 105 ± 3 mm **XL -** Width: 11 3 ± 3 mm	**XS -** Width: 76 ± 3 mm S- Width: 84± 3 mm **M-** Width: 94 ± 3 mm L - Width: 105 ± 3 mm **XL -** Width: 113 ± 3 111111	
Physical Properties	ASTM D 6319-10 Tensile, Elongation - Before Aging Range: Tensile Stren g th min: > 14 Mpa Ultimate Elongation Min: 500% After Aging Range: Tensile Strength min: > 14 Mpa Ultimate Elongation Min: 400%	Before Aging Result: 14 Mpa ,500% After Aging Result: 14 Mpa , 400%	Before Aging Result: 14 Mpa 500% After Aging Result: 14 Mpa 400%	Same
Thickness	ASTM D 6319-10 Range: Thickness (mm) Single wall (*All* Sizes) Finger: Typical Value: (0.10 - 0.1 2) Palm: Typical Value: (0.07 - 0.08)	Result: Finger: 0.10 ± 0.02 Palm: 0.07 ± 0.02	Result: Finger: 0.10 ± 0.02 Palm: 0.07 ± 0.02	Same

Powder Free	ASTM S 6319-10 Range: < 2 mg /glove	Result: XS: 0.6 mg / glove S: 0.8 mg / glove M: 1.2 mg/glove L: 0.6 mg /glove XL: 1.0 mg / glove	Result: XS: 0.6 mg / glove S: 0.8 mg / glove M: 1.2 mg/glove L: 0.6 mg /g love XL: 1.0 mg / glove	Same
Biocompatibility	Primary Skin Irritation - ISO 10993-10:2010 (E)	Under the condition on of study not an irritant	Under the condition of s study not an irritant	Same
	Dermal Sensitization Assay (Skin Maximization) - ISO 10993-10:2010 (E)	Under the condition of study not an irritant	Under the condition of study not an irritant	Same

Characteristics	Standards	Device Performance		Remarks
		Predicate	Subject	
Intended use	-	A patient examination glove is a disposable glove intended for medical purpose that is worn on the examiner' s hand or finger to prevent contamination between patient and exam in er.	A powder-free patient examination glove 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	-
Water Tight (1000 ml)	ASTM D 5151-06	AQL 2.5 PASSES	AQL 2.5 PASSES	Same
Material	ASTM D 6910-10	Nitrile	Nitrile	Same
Colour	-	Black, Orange	Black, Orange	Same
			Blue	Different
Available Sizes with colour		Black (XS, S, M, L, XL)	Black (XS, S, M, L, XL)	Same

		O range **(XS,S,M,L,XL)**	O range **(XS,S,M,L,XL)**	
			Blu e **(XS,S,M,L,XL)**	Different
Texture	-	Finger Texture	Finger Texture	Same
Sizes	**ASTM** D 6319-10	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Same
Single Use	Medical Glove Guidance Manual - Labelling	Single Use	Single Use	Same
Manufacturer		**GMP** Medicare Sdn Bhd, Malaysia	Megine Industries Sdn Bhd, Malaysia	-

7. SUMMARY OF NON-CLINCIAL TESTING SUMMARY:

The standards used for Megine Industries Sdn Bhd glove production are Based on the listed standards. All testing meets requirements for Physical and Dimensions testing conducted on gloves.

- **ASTM** D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- **ASTM** D5151-19 Standard Test Method for Detection of Hole s in Medical Gloves
- **ASTM** D6124 -06 Standard Test Method for Residual Powder on Medical Gloves
- **ASTM** D3578-05,2015 Standard Specification for Rubber Examination Gloves
- **ISO** 10993-10: 2010, Biological evaluation of medical de vices - Part 10: Test for irritation and Skin Sensitization
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Test for irritation and Skin Sensitization
- ISO 1522 3-1:2016, Medical Devices - Symbols to be used with medical device labels, labelling ad information to be supplied - Part I: General Requirements.

There are no special labeling claims and there is no claim as hypoallergic on the labels.

a) Performance Data -

Test Method	Purpose	Acceptance Criteria	Result

ASTM D 6319- 10 (Reapproved 2015) Standard specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 230 mm	>230 mm (Passes)
ASTM D 6319-10 (Reapproved 2015) Standard specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	95 ± 10 mm	98 ± 2 mm (Passes)
ASTM D 6319-10 (Reapproved 2015)	To determine the thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min	Palm: 0.09 mm (Passes)
Standard specification for Nitrile Examination Gloves for Medical Application			Finger: 0.12 mm (Passes)
ASTM D 6319-10 (Reapproved 2015) Standard specification for Nitrile Examination Gloves for Medical Application	To determine the physical properties Tensile strength	Before Ageing: Tensile strength 14Mpa min After Ageing: Ultimate elongation 400 % min	24.5 Mpa (Passes) 590% (Passes)
ASTM D 5151-06 (Reapproved 2015) Standard Test method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	AQL 2.5 (Passes)
ASTM D 6124-06 (Standard Test Method for Residual Powder on medical Gloves)	To determine the amount of residual powder and non-powder solids found on gloves	Less than 2 mg per glove	0.60 mg / glove (P asses)
ASTM D 3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the specifications for rubber examination gloves	Dimension, AQL: 4.0 Length: min 230 mm Force at Break, AQL: 4.0, Tensile and Modul us	Meet the requirements of ASTM 3578 until 5 years (Passes)

b) Bio-Compatibility Data

Test Method	Purpose	Acceptance Criteria	Re s ult

ISO 1099 3-10 Biological Evaluation of Medic al Device Test for Irritation and Skin Sensitization. Test done for Irritation.	To deter mine the potential irritation of the effect likely to arise from a single exposure of test material on the intact skin of rabbits.	Under the condition of study not an irritant	Under the condition of study not an irritant
ISO 10993-10 Biological Evaluation of Medical De vice Test for Irritation and Skin Sensitization. Test done for sensitization.	To evaluate the potential of a test material to cause a delayed hypersensitivity reaction (Type IV) following exposure of the skin of guinea pigs.	Under the condition of study not an irritant	Under the condition of study not an irritant

8. Discussion of Clinical tests performed:
   Not Applicable - Clinical Data is not needed for Gloves or for most devices cleared by the 510 (K) process.

9. Conclusion:

   The conclusion drawn from the nonclinical test demonstrate that the subject device in 510 **(K)** submission Kl 72867. AMADEX Nitrile Powder Free Examination Gloves Non-Sterile, (Blue, Black, and Orange) is as safe, as effective, and performs as well as or better than the legally marketed predicate device.