April 11, 2022

AAMedix Glove Sdn Bhd
Annette Schaps
Regulatory Consultant
Unit 19D, Level 19, No.16, Persiaran Setia Dagang Bander
Setia Alam, 40170 Shah Alam
Selanger Darul Ehsan, 40170
Malaysia

Re: K220121
Trade/Device Name: Non Sterile Nitrile Powder Free Examination Gloves - Blue,Green, and Black
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: January 13, 2022
Received: January 18, 2022

Dear Annette Schaps:

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,

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)*

K220121

Device Name
NON STERILE NITRILE POWDER FREE EXAMINATION GLOVES – BLUE, GREEN AND BLACK

Indications for Use *(Describe)*

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.

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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008 - 1

AAMedix Glove Sdn Bhd

NON STERILE NITRILE POWDER FREE EXAMINATION

GLOVES – BLUE, GREEN AND BLACK

510(K) Summary

510K SUMMARY

Date of Summary Prepared: March 23, 2022

510K Number: K220121

1. **Applicant** : AAMedix Glove Sdn Bhd

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Official Correspondence: Annette Schaps

2. **Device Name**: Non Sterile Nitrile Powder Free Examination Gloves – Blue, Green And Black color.

Trade Name: Non Sterile Nitrile Powder Free Examination Gloves – Blue, Green and Black color.

Common Name: Nitrile Examination Gloves

3. Regulatory Information

Classification Name	:	Nitrile Powder Free Examination Gloves
Classification	:	Class I
Product Code	:	LZA
Regulation Number	:	21 CFR 880.6250

4. Predicate Device

510K Number	:	K143289- YTY Industry (Manjung) Sdn. Bhd.
Device Name	:	Non Sterile, Powder Free Nitrile Examination Gloves - Orange, Green, Blue and Violet Color.

5. Intended Use

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.

6. Description

The Powder Free Nitrile Examination Gloves are non sterile, single use, and disposable. These gloves are available in Blue, Green, and Black colors. This device is to protect the examiner and prevent contamination between patient and the examiner when properly worn. The sizes of the gloves are Small, Medium, Large and X-Large. Non Sterile Nitrile Powder Free Examination Gloves meet all current specifications listed under ASTM Specifications D6319.

Summary of Comparison and Technological Characteristic			
Table 1 - General Comparison			
	SUBJECT DEVICE: K220121	**PREDICATE DEVICE: K143289**	**Comparison**
Company Name	**AAMedix Glove Sdn Bhd**	**YTY INDUSTRY (MANJUNG) SDN. BHD**	
Product Name	Non Sterile, Powder Free Nitrile Examination Gloves-BLUE, GREEN AND BLACK	Non Sterile, Powder Free Nitrile Examination Gloves-Orange, Green, Blue and Violet Color	
Available Colors	Blue, Green and Black	Blue, Green and Others	Similar
Available Sizes	Small, Medium, Large and X-Large	Not specified but data provided on Medium	Similar
Indications for Use	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.	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Similar
MATERIALS	Carboxylated Butadiene Acrylonitrile as base material	Carboxylated Butadiene Acrylonitrile as base material	Same
DIMENSIONS	Meets ASTM D6319 Criteria	Meets ASTM D6319 Criteria	Same
PHYSICAL PROPERTIES	Meets ASTM D6319 Criteria	Meets ASTM D6319 Criteria	Same
FREEDOM FROM HOLES/Watertight	Meets ASTM D6319/ASTM D5151 Criteria	Meets ASTM D5151 Criteria	Same
POWDER FREE/Residual Powder	Meets ASTM D6319 Criteria	Meets ASTM D6319 Criteria	Same
BIOCOMPATABILITY	Per ISO 10993-10: Non-irritant (Response Category is Negligible) and Non-sensitizer (No sensitization) Per ISO 10993-11: Acute Systemic Toxicity; No toxic effects	Per ISO 10993-10: Non-irritant and Non-sensitizer	Same
Product Common Name	Non sterile Nitrile Powder Free Examination Gloves	Non sterile Nitrile Powder Free Examination Gloves	Same
Product Code/Class	LZA	LZA	Same

	Class I (21 CFR 880.6250)	Class I (21 CFR 880.6250)	
Sterility/Use	Non-Sterile/Single Use	Non-Sterile/Single Use	Same
OTC Use	Yes	Yes	Same

Table 2 Specifications and Performance Test Results Comparison

		SUBJECT DEVICE: K220121	**PREDICATE DEVICE: K143289**	**Comparison**
		AAMedix Glove Sdn Bhd	**YTY INDUSTRY (MANJUNG) SDN. BHD**	
Glove Color/Size		BLUE/Medium	BLUE/Medium	
DIMENSION	**ASTM D6319 Accept Criteria**			
Overall Length	230 mm Minimum	240-246 mm	240-250 mm	Same
Width	95 +/-10 mm	95-98 mm	95-99 mm	Same
Palm Thickness	0.05 mm Minimum	0.06-0.06 mm	0.05-0.06 mm	Same
Finger thickness	0.05 mm Minimum	0.09-0.10 mm	0.09-0.10 mm	Same
PHYSICAL PROPERTIES				
Tensile Strength (before aging)	14 MPa, Minimum	25.9-32.0 MPa	28.46-33.44 MPa	Same
Tensile Strength (after aging)	14 MPa, Minimum	25.4-34.0 MPa	29.76-34.18 MPa	Same
Ultimate Elongation (before aging)	500 % Minimum	500-540 %	520-580 %	Same
Ultimate Elongation (after aging)	400 % Minimum	480-520 %	440-520 %	Same
FREEDOM FROM HOLES/Watertight	Per ASTM D5151-06 (2011)	Holes Found: 0	Holes found: 0 (Accept 1, Reject 7)	Same
Pinhole AQL	Inspection Level G-1; AQL=2.5	Inspection Level G-1; AQL=2.5	Inspection Level G-1; AQL=2.5	Same
POWDER FREE/Residual Powder	Residue limit of 2.0 mg/glove	0.70 mg/glove	0.20 mg/glove	Same

Summary of Nonclinical Testing:

Table 3 Summary of Device Specifications and Performance Results

	ASTM D6319 Requirement	BLUE Gloves	GREEN Gloves	BLACK Gloves
DIMENSIONS				
Overall Length				
-Small	220 mm minimum	Pass (242-253 mm)	Pass (237-243 mm)	Pass (239-248 mm)
-Medium	230 mm minimum	Pass (240-246 mm)	Pass (240-247 mm)	Pass (244-251 mm)
-Large	230 mm minimum	Pass (245-255 mm)	Pass (240-247 mm)	Pass (243-251 mm)
-X large	230 mm minimum	Pass (243-253 mm)	Pass (240-250 mm)	Pass (241-277 mm)
Width				
-Small	80 +/-10 mm	Pass (85-87 mm)	Pass (86-88 mm)	Pass (85-86 mm)
-Medium	95 +/-10 mm	Pass (95-98 mm)	Pass (95-96 mm)	Pass (95-97 mm)
-Large	110 +/-10 mm	Pass (106-109 mm)	Pass (106-106 mm)	Pass (105-106 mm)
-X large	120 +/-10 mm	Pass (113-115 mm)	Pass (114-116 mm)	Pass (115-115 mm)
Palm Thickness				
-Small	0.05 mm minimum	Pass (0.06-0.07 mm)	Pass (0.12-0.14 mm)	Pass (0.07-0.08 mm)
-Medium	0.05 mm minimum	Pass (0.06-0.06 mm)	Pass (0.13-0.13 mm)	Pass (0.07-0.07 mm)
-Large	0.05 mm minimum	Pass (0.05-0.07 mm)	Pass (0.11-0.13 mm)	Pass (0.07-0.07 mm)
-X large	0.05 mm minimum	Pass (0.06-0.06 mm)	Pass (0.12-0.13 mm)	Pass (0.06-0.07 mm)
Finger thickness				
-Small	0.05 mm minimum	Pass (0.09-0.11 mm)	Pass (0.15-0.17 mm)	Pass (0.11-0.13 mm)
-Medium	0.05 mm minimum	Pass (0.09-0.10 mm)	Pass (0.15-0.18 mm)	Pass (0.11-0.13 mm)
-Large	0.05 mm minimum	Pass (0.10-0.11 mm)	Pass (0.15-0.16 mm)	Pass (0.11-0.13 mm)
-X large	0.05 mm minimum	Pass (0.10-0.11 mm)	Pass (0.15-0.16 mm)	Pass (0.11-0.14 mm)

	ASTM D6319 Requirement	BLUE Gloves	GREEN Gloves	BLACK Gloves
PHYSICAL PROPERTIES				
Tensile Strength (Before Aging)				
-Small	14 MPa minimum	Pass (25.2-31.9 MPa)	Pass (24.1-34.1 MPa)	Pass (33.5-41.2 MPa)
-Medium	14 MPa minimum	Pass (25.9-32.0 MPa)	Pass (25.9-32.0 MPa)	Pass (34.3-46.5 MPa)
-Large	14 MPa minimum	Pass (23.9-34.3 MPa)	Pass (21.2-28.8 MPa)	Pass (31.6-42.2 MPa)
-X large	14 MPa minimum	Pass (28.2-39.2 MPa)	Pass (19.6-29.9 MPa)	Pass (25.2-43.5 MPa)
Tensile Strength (After Aging)				
-Small	14 MPa minimum	Pass (25.6-34.9 MPa)	Pass (24.4-38.1 MPa)	Pass (25.7-43.5 MPa)
-Medium	14 MPa minimum	Pass (25.4-34.0 MPa)	Pass (24.8-32.3 MPa)	Pass (34.7-45.8 MPa)
-Large	14 MPa minimum	Pass (24.0-37.4 MPa)	Pass (20.7-33.9 MPa)	Pass (35.1-43.0 MPa)
-X large	14 MPa minimum	Pass (33.2-40.2 MPa)	Pass (21.6-32.1 MPa)	Pass (24.7-44.8 MPa)
Ultimate Elongation (Before Aging)				
-Small	500% minimum	Pass (500-540%)	Pass (500-580%)	Pass (540-600%)
-Medium	500% minimum	Pass (500-540%)	Pass (500-560%)	Pass (520-600%)
-Large	500% minimum	Pass (500-560%)	Pass (500-580%)	Pass (520-600%)
-X large	500% minimum	Pass (500-560%)	Pass (540-580%)	Pass (460-540%)
Ultimate Elongation (After Aging)				
-Small	400% minimum	Pass (480-520%)	Pass (460-540%)	Pass (540-580%)
-Medium	400% minimum	Pass (480-520%)	Pass (460-540%)	Pass (520-600%)
-Large	400% minimum	Pass (480-520%)	Pass (480-560%)	Pass (520-560%)
-X large	400% minimum	Pass (480-520%)	Pass (500-560%)	Pass (440-520%)

	ASTM D6319 Requirement	BLUE Gloves	GREEN Gloves	BLACK Gloves
FREEDOM FROM HOLES (Pinhole Inspection)				
-Small	AQL=2.5; Accept on 10 (n=200)	Pass (Found=1)	Pass (Found=0)	Pass (Found=2)
-Medium	AQL=2.5; Accept on 7 (n=200)	Pass (Found=0)	Pass (Found=0)	Pass (Found=0)
-Large	AQL=2.5; Accept on 10 (n=200)	Pass (Found=1)	Pass (Found=1)	Pass (Found=0)
-X Large	AQL=2.5; Accept on 10 (n=200)	Pass (Found=0)	Pass (Found=6)	Pass (Found=1)

	ASTM D6319 Requirement	BLUE Gloves	GREEN Gloves	BLACK Gloves
POWDER FREE/Powder Content				
-Small	does not exceed 2 mg per glove	Pass (Average: 0.36 mg per glove)	Pass (Average: 0.18 mg per glove)	Pass (Average: 0.04 mg per glove)
-Medium	Does not exceed 2 mg per glove	Pass (Average: 0.70 mg per glove)	Pass (Average: 0.10 mg per glove)	Pass (Average: 0.06 mg per glove)
-Large	Does not exceed 2 mg per glove	Pass (Average: 0.30 mg per glove)	Pass (Average: 0.16 mg per glove)	Pass (Average: 0.04 mg per glove)
-X Large	Does not exceed 2 mg per glove	Pass (Average: 1.02 mg per glove)	Pass (Average: 0.24 mg per glove)	Pass (Average: 0.10 mg per glove)

7. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device, *AAMedix Glove Sdn Bhd* NON STERILE NITRILE POWDER FREE EXAMINATION GLOVES – BLUE, GREEN AND BLACK , is as safe, as effective, and performs as well as or better than the legally marketed device, YTY INDUSTRY (MANJUNG) SDN. BHD Non Sterile, Powder Free Nitrile Examination Gloves- Orange, Green, Blue and Violet Color (cleared per 510(K) K143289).