December 16, 2021

AT Glove Engineering SDN. BHD
Manoj Zacharias
US Agent
Liberty Management Group Limited
75 Executive Drive Suite 114
Aurora, Illinois 60504

Re: K212645
Trade/Device Name: At Nitrile Examination Glove Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 15, 2021
Received: November 17, 2021

Dear Manoj Zacharias:

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, 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)*
K212645

Device Name
AT Nitrile Examination Glove Powder Free

Indications for Use *(Describe)*

AT Nitrile Examination Glove Powder Free is a disposable device intended for medical purpose that is 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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AT GLOVE ENGINEERING SDN. BHD. 202001014272 (1370592-K)
No. 9, Jalan Chepor 11/7, Kawasan Perusahaan Seramik Chepor,
31200, Chemor, Perak, Malaysia
Tel : +605-2014882
URL : www.atsys.com.my

510(k) SUMMARY (K212645)

[AS REQUIRED BY 21CFR807.92]

I. SUBMITTER DETAILS

510(k) Owner's Name	:	AT GLOVE ENGINEERING SDN. BHD
Address	:	No.9, Jalan Chepor 11/7, Kawasan Perusahaan Seramik Chepor, 31200, Chemor Perak, Malaysia
Telephone	:	+605 201 4882
Fax Number	:	+605 201 4882
Contact person	:	Mr. Choong Lee Aun
Designation	:	Managing Director
Contact Number	:	00 60 124055026
Contact Email	:	la.choong@atsys.com.my
Date of Summary Prepared	:	December 6, 2021

II. DEVICE DETAILS

Device Trade Name	:	AT
Device Common Name	:	Nitrile Examination Glove Powder Free
Device Classification name	:	Non-powdered patient examination glove
Regulation Number	:	21 CFR 880.6250
Class	:	I
Product Code	:	LZA

III. PREDICATE DEVICE DETAILS

Predicate Device Name	:	Disposable Nitrile Gloves
510(k) Number	:	K210276
Regulation Number	:	880.6250
Class	:	I
Product Code	:	LZA

IV. DEVICE DESCRIPTION

AT Nitrile Examination Glove Powder Free is a Class I device bearing the product code LZA (21CFR 880.6250). They meet all the current specifications listed under the ASTM D6319 -19, Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from acrylonitrile-butadiene copolymer dispersion. These gloves are Violet blue in color having Finger Texture and Ambidextrous and are powder free. The product is non-sterile.

V. INDICATIONS FOR USE

AT Nitrile Examination Glove Powder Free is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K212645	K210276	-
2.	Manufacturer	AT GLOVE ENGINEERING SDN. BHD	FUJIAN ERCON MEDICAL MANAGEMENT CO., LTD.	-
3.	Classification	I	I	Same
4.	Regulation number	21 CFR 880.6250	21 CFR 880.6250	Same
5.	Product Code	LZA	LZA	Same
6.	Indication For Use	AT Nitrile Examination Glove Powder Free is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	The Disposable Nitrile Gloves are intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
7.	Material	Nitrile	Nitrile	Same
8.	Color	Violet Blue	Blue	Different
9.	Texture	Finger Texture	Finger texture	Same
10.	Ambidextrous	Yes	Yes	Same
11.	Size	S, M, L, XL	S, M, L, XL	Same
12.	OTC Use	Yes	Yes	Same
13.	Reusability	Single use	Single use	Same

Sl. No	Features compared		Proposed Device	Predicate Device	Result
14.	Sterility		Non- sterile	Non- sterile	Same
15.	Dimensions		Length Min 230 m Width Min 95±10 Mm (for medium size)	Length Min 230 m Width Min 95±10 Mm (for medium size)	Same
16.	Thickness		Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
17.	Physical Properties		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
18.	Detection of Holes		Passes AQL 2.5	Passes AQL 2.5	Same
19.	Powder Free Residue		≤2 mg/glove	≤2 mg/glove	Same
20.	Biocompatibility Study	In Vitro Cytotoxicity	Under the conditions of the study, cytotoxic. Additional Testing was performed to determine if this was a systemic toxicity concern.	Under the conditions of the study, non-cytotoxic.	Same
		Skin Sensitization	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
		Skin Irritation	Under the condition of study not an irritant	Under the condition of study not an irritant	Same
		Acute Systemic Toxicity	Under the condition of study, the device extracts do not pose a systemic toxicity.	Data not available	Different
		Material Mediated Pyrogenicity	Under the conditions of the study, the device demonstrate a non-pyrogenic response.	Data not available	Different

DISCUSSION OF DIFFERENCES:

Different: The color of the proposed device is violet blue whereas predicate device is blue. The color variation of the proposed device and predicate devices doesn't affect the safety and efficiency of the device.

The Performance Tests and Biocompatibility Tests demonstrated that AT Nitrile Examination Glove Powder Free met all acceptance criteria and has the similar indications for use, design, materials, technical characteristics and performance properties as compared to the predicate device. No new safety or effectiveness issues were raised during the testing program and therefore, this device may be considered substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

A. Non- Clinical Data

Performance Tests

AT Nitrile Examination Glove Powder Free is subjected to the following performance tests according to the requirements of Guidance for Industry and FDA Staff - Medical Glove Guidance Manual and found to be safe and efficient with respect to its intended use:

- Dimension
- Physical property
- Barrier property tests
  - ➢ Detection of Holes in Medical Gloves
- Powder Free Residue

Table 2: Performance Testing Summary

<table>
<tr><th></th><th>Tests</th><th colspan="3">Proposed Device
Actual Data</th><th colspan="3">Acceptance Criteria</th><th>Result</th></tr>
<tr><td rowspan="11">1.</td><td rowspan="11"><u>Dimension</u>

Length, Width and Thickness

ASTM D6319-19
Standard Specification for
Nitrile Examination Gloves for
Medical Application</td><td>Size</td><td>Length</td><td>Width</td><td>Size</td><td>Length</td><td>Width</td><td rowspan="11">Pass</td></tr>
<tr><td>S</td><td>247.76 mm</td><td>84.84 mm</td><td>S</td><td rowspan="4">230 mm</td><td>80±10 mm</td></tr>
<tr><td>M</td><td>249.53 mm</td><td>94.46 mm</td><td>M</td><td>95±10 mm</td></tr>
<tr><td>L</td><td>253.46 mm</td><td>105 mm</td><td>L</td><td>110±10 mm</td></tr>
<tr><td>XL</td><td>243.53 mm</td><td>113.15 mm</td><td>XL</td><td>120±10 mm</td></tr>
<tr><td colspan="3">Thickness</td><td colspan="3">Thickness</td></tr>
<tr><td>Size</td><td>Palm</td><td>Finger</td><td>Size</td><td>Palm</td><td>Finger</td></tr>
<tr><td>S</td><td>0.06 mm</td><td>0.09 mm</td><td>S</td><td rowspan="4">0.05 mm</td><td rowspan="4">0.05 mm</td></tr>
<tr><td>M</td><td>0.06 mm</td><td>0.09 mm</td><td>M</td></tr>
<tr><td>L</td><td>0.07 mm</td><td>0.10 mm</td><td>L</td></tr>
<tr><td>XL</td><td>0.06 mm</td><td>0.09 mm</td><td>XL</td></tr>
<tr><td rowspan="11">2.</td><td rowspan="11"><u>Physical property</u>

Tensile strength and
Ultimate Elongation

ASTM D6319-19
Standard Specification for
Nitrile Examination Gloves for
Medical Application</td><td colspan="3">Tensile Strength</td><td colspan="3">Tensile Strength</td><td rowspan="11">Pass</td></tr>
<tr><td>Size</td><td>Before Aging</td><td>After Aging</td><td>Size</td><td>Before Aging</td><td>After Aging</td></tr>
<tr><td>S</td><td>31.57 MPa</td><td>29.38 MPa</td><td>S</td><td rowspan="4">14 MPa</td><td rowspan="4">14 MPa</td></tr>
<tr><td>M</td><td>27.33 MPa</td><td>29.92 MPa</td><td>M</td></tr>
<tr><td>L</td><td>30.58 MPa</td><td>29.91 MPa</td><td>L</td></tr>
<tr><td>XL</td><td>28.06 MPa</td><td>30.40 MPa</td><td>XL</td></tr>
<tr><td colspan="3">Ultimate Elongation</td><td colspan="3">Ultimate Elongation</td></tr>
<tr><td>Size</td><td>Before Aging</td><td>After aging</td><td>Size</td><td>Before Aging</td><td>After aging</td></tr>
<tr><td>S</td><td>534.61%</td><td>544.61%</td><td>S</td><td rowspan="4">500%</td><td rowspan="4">400%</td></tr>
<tr><td>M</td><td>561.53%</td><td>550.76%</td><td>M</td></tr>
<tr><td>L</td><td>521.53%</td><td>499.23%</td><td>L</td></tr>
<tr><td>XL</td><td>546.15%</td><td>517.69%</td><td>XL</td></tr>
</table>

3.	**Barrier property tests Detection of Holes in Medical Gloves** ASTM D6319-19 /ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	S M L XL	AQL 2.5	S M L XL	AQL 2.5	**Pass**
4.	**Powder Free Residue** ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	**Size**	**Residual Powder Content**	**Size**	**Residual Powder Content**	**Pass**
		S	0.22 mg/glove	S	≤2 Mg/glove	
		M	0.36 mg/glove	M		
		L	0.10 mg/glove	L		
		XL	0.36 mg/glove	XL		

B. Biocompatibility

The materials used in the AT Nitrile Examination Glove Powder Free are biocompatible based on the biocompatibility tests mentioned in the Guidance for Industry and FDA Staff - Medical Glove Guidance Manual:

- In Vitro Cytotoxicity
- Skin Sensitization
- Skin Irritation
- Acute systemic Toxicity
- Material Mediated Pyrogenicity

These tests were performed according to ISO 10993-1:2018, Biological Evaluation of Medical Devices - Part 1, Evaluation and Testing within a Risk Management Process.

Table 3: Biocompatibility Test Summary

Sl. No	Test Performed	Standard	Proposed Device	Result
1.	In Vitro Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, cytotoxic. Additional Testing was performed to determine if this was a systemic toxicity concern.	Pass
2.	Skin Sensitization	ISO 10993-10:2010	Under the conditions of the study not a sensitizer	Pass
3.	Skin Irritation	ISO 10993-10:2010	Under the condition of study not an irritant.	Pass
4.	Acute systemic Toxicity	ISO 10993-11:2017	Under the condition of study, the device extracts do not pose a systemic toxicity concern	Pass
5.	Material Mediated Pyrogenicity	ISO 10993-11:2017	Under the conditions of the study, the device demonstrate a non-pyrogenic response.	Pass

C. Clinical Test Data

Clinical study was not conducted as clinical data is not needed for AT Nitrile Examination Glove Powder Free.

VIII. CONCLUSION

The conclusion drawn from the non-clinical tests demonstrate that the subject device, AT Nitrile Examination Glove Powder Free are as safe, as effective and perform as well as or better than legally marketed predicated device in K210276