December 18, 2021

Ammex Corporation
Davendran Tangaya
Manager of Compliance & Product Development
1019 W James St, Suite 200
Kent, Washington 98032

Re: K211457
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue, Black, Indigo)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 20, 2021
Received: November 26, 2021

Dear Davendran Tangaya:

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)*
K211457

Device Name
Powder Free Nitrile Examination Gloves (Blue, Black, Indigo)

Indications for Use *(Describe)*
The Powder Free Nitrile Examination Gloves (Blue, Black, Indigo) is a disposable device intended for medical purpose that is worn on the examiner's hands 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

The assigned 510(k) Number: K211457

1. Date of Preparation: 16 Dec 2021

2. Sponsor

Ammex Corporation

1019 W James St #200, Kent, WA 98032, United States

Contact Person: Sasitharan Nair

Position: Senior VP of Global Sourcing and Product Innovation

Tel: + 425-251-4000

Fax: + 425-251-4621

Email: snair@ammex.com

3. Submission Correspondent

Ammex Corporation

1019 W James St #200, Kent, WA 98032, United States

Contact Person: Davendran

Position: Manager of Compliance & Product Development

Tel: + 425-251-4000

Fax: + 425-251-4621

Email: dtangaya@ammex.com

4. Proposed Device Identification

Trade Name: Powder Free Nitrile Examination Gloves (Blue, Black, Indigo)

Common Name: Nitrile Patient Examination Gloves (Powder Free)

Regulatory Information:

Classification: I

Product Code: LZA

Regulation Number: 21 CFR 880.6250

Product Name: Powder Free Nitrile Examination Gloves (Blue, Black, Indigo)

Indication for Use Statement:

The Powder Free Nitrile Examination Gloves (Blue, Black, Indigo) is a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: K150340

Classification: I

Product Code: LZA

Regulation Number: 21 CFR 880.6250

Product Name: Powder Free Nitrile Gloves (White, Cobalt Blue, Black, Ice Blue)

Manufacturer: HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD

6. Device Description

The proposed device, Powder Free Nitrile Examination Gloves (Blue, Black, Indigo) are disposable devices intended for medical purposes that is worn on the examiner’s hands to prevent contamination between patient and examiner.

The proposed devices are Powder Free Nitrile Examination Gloves and includes variations of different size and color. The colors of the proposed device are Blue, Black, and Indigo.

Product Reference Number: APFN4X100 (Blue)

Product Reference Number: ABNPF4X100 (Black)

Product Reference Number: AINPF4X100 (Indigo)

7. Technological Characteristics Comparison with predicate device (Blue)

A. Powder Free Nitrile Examination Gloves - Blue

Table 1: Device Size Specifications

Size	Length (mm)	Width (mm)	Thickness (mm)		
Extra Small	≥ 230	75 ± 5 mm	Finger 0.10±0.02	Palm 0.08±0.02	Cuff 0.06±0.02
Small		85 ± 5 mm			
Medium		95 ± 5 mm			
Large		105 ± 5 mm			
Extra Large		115 ± 5 mm			
Color	**Blue**				

Table 2: Performance and Physical Specifications (For XS, S, M, L, XL)

Property	Unit	Conditioning	Specification	Pinhole AQL
Tensile Strength	MPa	Unaged	≥ 14	≤ 2.5
Elongation at Break	%		≥ 500	
Tensile Strength	MPa	Aged	≥ 14	
Elongation at Break	%		≥ 400	

Discussion: The above data of size, performance, and physical specifications of proposed gloves meet all the current specifications listed in the ASTM standard D6319

Table 3: Device General Comparison Table

Characteristics and Parameters	Proposed Device: Powder Free Nitrile Examination Gloves (Blue)	Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue)	Comparison
510(k) number	K211457	K150340	Different
Product Code	LZA	LZA	Same

Intended Use	The Powder Free Nitrile Examination Gloves is a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Powder Free Nitrile Gloves (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Classification	Class 1	Class 1	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Raw Rubber Material	Nitrile (Acrylonitrile-butadiene)	Nitrile (Acrylonitrile-butadiene)	Same
Surface Treatment / Powder or Powder Free	Powder Free	Powder Free	Same
Surface Appearance	1. Ambidextrous 2. Finger Textured	1. Ambidextrous 2. Finger Textured	Same
Color	Blue	White, Cobalt Blue, Black & Ice Blue	Different Colors

Table 4: Device Dimension Comparison Table

Proposed Device: Powder Free Nitrile Examination Gloves (Blue) (K211457)	Designation	XS	S	M	L	XL	Tolerance
	Length, mm	230	230	230	230	230	Minimum
	Width, mm	75	85	95	105	115	± 10
	Thickness, mm						
	Finger	0.10-0.12					±0.02
	Palm	0.08-0.10					±0.02
	Cuff	0.06-0.07					±0.02
Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue) (K150340)	Designation	XS	S	M	L	XL	Tolerance
	Length, mm	230	230	230	230	230	Minimum
	Width, mm	70	80	95	110	120	± 10
	Thickness, mm						
	Finger	0.10-0.12					±0.03
	Palm	0.08-0.10					±0.03
	Cuff	0.06.0.09					±0.03

Discussion: The sizes and tolerances of proposed device are different with those of the predicate.

Table 5: Device Performance Comparison

Characteristics and Parameters	Proposed Device: Powder Free Nitrile Examination Gloves (Blue) (K211457)	Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue) (K150340)	Comparison
Tensile Strength (before age) Minimum 14 MPa	Min 14 MPa	Min 14 MPa	Meeting requirement of Tensile Strength under ASTM D6319
Tensile Strength (after age) Minimum 14 MPa	Min 14 MPa	Min 14 MPa	Meeting requirement of Tensile Strength under ASTM D6319
Ultimate Elongation (before age) Minimum 14 MPa	Min 500%	Min 500%	Meeting requirement of elongation under ASTM D6319
Ultimate Elongation (after age) Minimum 14 MPa	Min 400%	Min 400%	Meeting requirement of elongation under ASTM D6319
Freedom of Holes Meet AQL 2.5 at G1	Meet AQL 1.5 with G1	Meet AQL 1.5 with G1	Meeting requirement of freedom of holes under ASTM D6319
Residual powder test (Less than 2mg / glove)	Average powder residue for each size: S: 0.30 mg/glove M: 0.31 mg/glove L: 0.45 mg/glove	Contained less than 2 mg/glove	Meeting requirement of powder residue under ASTM D6319
Primary Skin Irritation (Surface-contacting, less than 24 hours duration)	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Yes, both are tested to be non-irritant
Dermal Sensitization (Surface-contacting, less than 24 hours duration)	Under the conditions of study, not a sensitizer	Under the conditions of study, not a sensitizer	Yes, both are tested to be non-sensitizer

In Vitro Cytotoxicity (Surface-contacting, less than 24 hours duration)	Under the conditions of study, non-cytotoxic	Not tested	The predicate device was not tested for In Vitro Cytotoxicity
Intracutaneous Reactivity	Under the conditions of study, not an irritant	Not tested	The predicate device was not tested for Intracutaneous reactivity

Discussion: The proposed device has different color to the predicate device.

8. Summary of Non-Clinical Performance Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Table 6: Summary of Non-Clinical Performance Testing

Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Sensitization Test: Provided gradesLess than 1.0 (<1.0), otherwise sensitization. 0- No visible change 1- Discrete erythema 2- Moderate erythema 3- Intense erythema	Under the conditions of this study, the gloves showed no evidence of causing skin contact sensitization.
		Scoring: Less than 1.0 (<1.0), no erythema /oedema. Since the scoring is less than 1, the response category is negligible. 0- No erythema /oedema 1- Slight erythema /oedema 2- Well defined erythema /oedema	Under the condition of this study, there was no erythema/ edema. The gloves are considered non-irritant.

		3- Moderate erythema /oedema 4- Severe erythema /oedema	
ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	For biocompatible, if the number of viable L929 mouse fibroblasts counts in direct method should be more than 70% to pass the test.	The study finds that the cells beneath the test samples incubated for 72 hours did not show any signs of cytotoxicity. The glove is non-cytotoxic to L-292 cell lines.
ISO 10993-10: 2010 Biological Evaluation of Medical Devices- Test for Irritation and Skin Sensitization—part 10: Tests for Intracutaneous Reactivity	The test article identified below was evaluated for intracutaneous reactivity potential on single topical application.	The requirements of the test were met if the difference between the test extract mean score and control mean score was 1.0 or less. 0- No erythema /oedema 1- Slight erythema /oedema 2- Well defined erythema /oedema 3- Moderate erythema /oedema 4- Severe erythema /oedema	Under the conditions of this study, there was no erythema and no edema. The glove is considered a non- irritant.
ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves.	Powder residue limit of 2.0 mg	Requirement met.

ASTM D5151 06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.	This test method covers the detection of holes in medical gloves.	Samples number: 500 gloves AQL: 2.5 (ISO 2859) Criterion ≤ 21 gloves for water leakage	Requirement met.

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Photograph of Powder Free Nitrile Examination Gloves (Blue)

Product Reference Number: APFN4X100
('X' on the Product Reference Number denotes the size of the glove, please refer Attachment 15)

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device, (K211457: Powder Free Nitrile Examination Gloves, in Blue is as safe, as effective, and performs as well as or better than the legally marketed predicated device, (K150340: Powder Free Nitrile Examination Gloves in White, Cobalt Blue, Black, and Ice Blue.

12. Summary comparing technological characteristics with predicate device (Black)

B. Powder Free Nitrile Examination Gloves – Black

Table 7: Device Size Specifications

Size	Length (mm)	Width (mm)	Thickness (mm)		
Extra Small	≥ 230	75 ± 5 mm	Finger 0.10±0.02	Palm 0.08±0.02	Cuff 0.06±0.02
Small		85 ± 5 mm			
Medium		95 ± 5 mm			
Large		105 ± 5 mm			
Extra Large		115 ± 5 mm			
Color	**Black**				

Table 8: Performance and Physical Specifications (For XS, S, M, L, XL)

Property	Unit	Conditioning	Specification	Pinhole AQL
Tensile Strength	MPa	Unaged	≥ 14	≤ 2.5
Elongation at Break	%		≥ 500	
Tensile Strength	MPa	Aged	≥ 14	
Elongation at Break	%		≥ 400	

Discussion: The above data of size, performance, and physical specifications of proposed gloves meet all the current specifications listed in the ASTM standard D6319

13. Technological Characteristic Comparison

Table 9: Device General Comparison Table

Characteristics and Parameters	Proposed Device: Powder Free Nitrile Examination Gloves (Black)	Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue)	Comparison
510(k) number	K211457	K150340	Different
Product Code	LZA	LZA	Same

Intended Use	The Powder Free Nitrile Examination Gloves is a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Powder Free Nitrile Gloves (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Classification	Class 1	Class 1	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Raw Rubber Material	Nitrile (Acrylonitrile-butadiene)	Nitrile (Acrylonitrile-butadiene)	Same
Surface Treatment / Powder or Powder Free	Powder Free	Powder Free	Same
Surface Appearance	3. Ambidextrous 4. Finger Textured	3. Ambidextrous 4. Finger Textured	Same
Color	Black	White, Cobalt Blue, Black & Ice Blue	Different Colors

Table 10: Device Dimension Comparison Table

Proposed Device: Powder Free Nitrile Examination Gloves (Black) (K211457)	Designation	XS	S	M	L	XL	Tolerance
	Length, mm	230	230	230	230	230	Minimum
	Width, mm	75	85	95	105	115	± 10
	Thickness, mm						
	Finger	0.10-0.12					±0.02
	Palm	0.08-0.10					±0.02
	Cuff	0.06-0.07					±0.02
Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue) (K150340)	Designation	XS	S	M	L	XL	Tolerance
	Length, mm	230	230	230	230	230	Minimum
	Width, mm	70	80	95	110	120	± 10
	Thickness, mm						
	Finger	0.10-0.12					±0.03
	Palm	0.08-0.10					±0.03
	Cuff	0.06.0.09					±0.03

Discussion: The sizes and tolerances of proposed device are different with those of the predicate.

Table 11: Device Performance Comparison

Characteristics and Parameters	Proposed Device: Powder Free Nitrile Examination Gloves (Black) (K211457)	Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue) (K150340)	Comparison
Tensile Strength (before age) Minimum 14 MPa	Min 14 MPa	Min 14 MPa	Meeting requirement of Tensile Strength under ASTM D6319
Tensile Strength (after age) Minimum 14 MPa	Min 14 MPa	Min 14 MPa	Meeting requirement of Tensile Strength under ASTM D6319
Ultimate Elongation (before age) Minimum 14 MPa	Min 500%	Min 500%	Meeting requirement of elongation under ASTM D6319
Ultimate Elongation (after age) Minimum 14 MPa	Min 400%	Min 400%	Meeting requirement of elongation under ASTM D6319
Freedom of Holes Meet AQL 2.5 at G1	Meet AQL 1.5 with G1	Meet AQL 1.5 with G1	Meeting requirement of freedom of holes under ASTM D6319
Residual powder test (Less than 2mg / glove)	Average powder residue for each size: S: 0.30 mg/glove M: 0.31 mg/glove L: 0.45 mg/glove	Contained less than 2 mg/glove	Meeting requirement of powder residue under ASTM D6319
Primary Skin Irritation (Surface-contacting, less than 24 hours duration)	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Yes, both are tested to be non-irritant
Dermal Sensitization (Surface-contacting, less than 24 hours duration)	Under the conditions of study, not a sensitizer	Under the conditions of study, not a sensitizer	Yes, both are tested to be non-sensitizer
In Vitro Cytotoxicity (Surface-contacting, less than 24 hours duration)	Under the conditions of study, non-cytotoxic	Not tested	The predicate device was not tested for In Vitro Cytotoxicity

Intracutaneous Reactivity	Under the conditions of study, not an irritant	Not tested	The predicate device was not tested for Intracutaneous reactivity

Discussion: The proposed device has different color to the predicate device.

14. Summary of Non-Clinical Performance Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Table 12: Summary of Non-Clinical Performance Testing

Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Sensitization Test: Provided gradesLess than 1.0 (<1.0), otherwise sensitization. 0- No visible change 1- Discrete erythema 2- Moderate erythema 3- Intense erythema	Under the conditions of this study, the gloves showed no evidence of causing skin contact sensitization.
		Scoring: Less than 1.0 (<1.0), no erythema /oedema. Since the scoring is less than 1, the response category is negligible. 0- No erythema /oedema 1- Slight erythema /oedema 2- Well defined erythema /oedema 3- Moderate erythema /oedema 4- Severe erythema /oedema	Under the condition of this study, there was no erythema/ edema. The gloves are considered non-irritant.

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	For biocompatible, if the number of viable L929 mouse fibroblasts counts in direct method should be more than 70% to pass the test.	The study finds that the cells beneath the test samples incubated for 72 hours did not show any signs of cytotoxicity. The glove is non-cytotoxic to L-292 cell lines.
ISO 10993-10: 2010 Biological Evaluation of Medical Devices- Test for Irritation and Skin Sensitization—part 10: Tests for Intracutaneous Reactivity	The test article identified below was evaluated for intracutaneous reactivity potential on single topical application.	The requirements of the test were met if the difference between the test extract mean score and control mean score was 1.0 or less. 0- No erythema /oedema 1- Slight erythema /oedema 2- Well defined erythema /oedema 3- Moderate erythema /oedema 4- Severe erythema /oedema	Under the conditions of this study, there was no erythema and no edema. The glove is considered a non- irritant.
ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves.	Powder residue limit of 2.0 mg	Requirement met.
ASTM D5151 06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.	This test method covers the detection of holes in medical gloves.	Samples number: 500 gloves AQL: 2.5 (ISO 2859) Criterion ≤ 21 gloves for water leakage	Requirement met.

15. Summary of Clinical Performance Test

No clinical study is included in this submission.

16. Photograph of Powder Free Nitrile Examination Gloves (Black)

Product Reference Number: ABNPF4X100
('X' on the Product Reference Number denotes the size of the glove, please refer Attachment 15)

17. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device, (K211457: Powder Free Nitrile Examination Gloves, in Black is as safe, as effective, and performs as well as or better than the legally marketed predicated device, (K150340: Powder Free Nitrile Examination Gloves in White, Cobalt Blue, Black, and Ice Blue.

18. Summary comparing technological characteristics with predicate device (Indigo)

C. Powder Free Nitrile Examination Gloves - Indigo

Table 13: Device Size Specifications

Size	Length (mm)	Width (mm)	Thickness (mm)		
Extra Small	≥ 230	75 ± 5 mm	Finger 0.10±0.02	Palm 0.08±0.02	Cuff 0.06±0.02
Small		85 ± 5 mm			
Medium		95 ± 5 mm			
Large		105 ± 5 mm			
Extra Large		115 ± 5 mm			
Color	**Indigo**				

Table 14: Performance and Physical Specifications (For XS, S, M, L, XL)

Property	Unit	Conditioning	Specification	Pinhole AQL
Tensile Strength	MPa	Unaged	≥ 14	≤ 2.5
Elongation at Break	%		≥ 500	
Tensile Strength	MPa	Aged	≥ 14	
Elongation at Break	%		≥ 400	

Discussion: The above data of size, performance, and physical specifications of proposed gloves meet all the current specifications listed in the ASTM standard D6319.

19. Technological Characteristics Comparison

Table 15: Device General Comparison Table

Characteristics and Parameters	Proposed Device: Powder Free Nitrile Examination Gloves (Indigo) (K211457)	Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue) (K150340)	Comparison
510(k) number	K211457	K150340	Different
Product Code	LZA	LZA	Same

Intended Use	The Powder Free Nitrile Examination Gloves is a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Powder Free Nitrile Gloves (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that are worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Classification	Class 1	Class 1	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Raw Rubber Material	Nitrile (Acrylonitrile-butadiene)	Nitrile (Acrylonitrile-butadiene)	Same
Surface Treatment / Powder or Powder Free	Powder Free	Powder Free	Same
Surface Appearance	0- Ambidextrous 1- Finger Textured	5. Ambidextrous 6. Finger Textured	Same
Color	Indigo	White, Cobalt Blue, Black & Ice Blue	Different Colors

Table 16: Device Dimension Comparison Table

Proposed Device: Powder Free Nitrile Examination Gloves (Indigo) (K211457)	Designation	XS	S	M	L	XL	Tolerance
	Length, mm	230	230	230	230	230	Minimum
	Width, mm	75	85	95	105	115	± 10
	Thickness, mm						
	Finger	0.10-0.12					±0.02
	Palm	0.08-0.10					±0.02
	Cuff	0.06-0.07					±0.02
Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue) (K150340)	Designation	XS	S	M	L	XL	Tolerance
	Length, mm	230	230	230	230	230	Minimum
	Width, mm	70	80	95	110	120	± 10
	Thickness, mm						
	Finger	0.10-0.12					±0.03
	Palm	0.08-0.10					±0.03
	Cuff	0.06.0.09					±0.03

Discussion: The sizes and tolerances of proposed device are different with those of the predicate.

Table 17: Device Performance Comparison

Characteristics and Parameters	Proposed Device: Powder Free Nitrile Examination Gloves (Indigo) (K211457)	Predicate Device: Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Black, Ice Blue) (K150340)	Comparison
Tensile Strength (before age) Minimum 14 MPa	Min 14 MPa	Min 14 MPa	Meeting requirement of Tensile Strength under ASTM D6319
Tensile Strength (after age) Minimum 14 MPa	Min 14 MPa	Min 14 MPa	Meeting requirement of Tensile Strength under ASTM D6319
Ultimate Elongation (before age) Minimum 14 MPa	Min 500%	Min 500%	Meeting requirement of elongation under ASTM D6319
Ultimate Elongation (after age) Minimum 14 MPa	Min 400%	Min 400%	Meeting requirement of elongation under ASTM D6319
Freedom of Holes Meet AQL 2.5 at G1	Meet AQL 1.5 with G1	Meet AQL 1.5 with G1	Meeting requirement of freedom of holes under ASTM D6319
Residual powder test (Less than 2mg / glove)	Average powder residue for each size: S: 0.30 mg/glove M: 0.31 mg/glove L: 0.45 mg/glove	Contained less than 2 mg/glove	Meeting requirement of powder residue under ASTM D6319
Primary Skin Irritation (Surface-contacting, less than 24 hours duration)	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Yes, both are tested to be non-irritant
Dermal Sensitization (Surface-contacting, less than 24 hours duration)	Under the conditions of study, not a sensitizer	Under the conditions of study, not a sensitizer	Yes, both are tested to be non-sensitizer
In Vitro Cytotoxicity (Surface-contacting, less than 24 hours duration)	Under the conditions of study, non-cytotoxic	Not tested	The predicate device was not tested for In Vitro Cytotoxicity

Intracutaneous Reactivity	Under the conditions of study, not an irritant	Not tested	The predicate device was not tested for Intracutaneous reactivity

Discussion: The proposed device has different color to the predicate device.

20. Summary of Non-Clinical Performance Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Table 18: Summary of Non-Clinical Performance Testing

Name of the Test Methodology / Standard	**Purpose**	**Acceptance Criteria**	**Results**
ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Sensitization Test: Provided gradesLess than 1.0 (<1.0), otherwise sensitization. 1- No visible change 2- Discrete erythema 3- Moderate erythema 4- Intense erythema	Under the conditions of this study, the gloves showed no evidence of causing skin contact sensitization.
		Scoring: Less than 1.0 (<1.0), no erythema /oedema. Since the scoring is less than 1, the response category is negligible. 0- No erythema /oedema 1- Slight erythema /oedema	Under the condition of this study, there was no erythema/ edema. The gloves are considered non-irritant.

		2- Well defined erythema /oedema 3- Moderate erythema /oedema 4- Severe erythema /oedema	
ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	For biocompatible, if the number of viable L929 mouse fibroblasts counts in direct method should be more than 70% to pass the test.	The study finds that the cells beneath the test samples incubated for 72 hours did not show any signs of cytotoxicity. The glove is non-cytotoxic to L-292 cell lines.
ISO 10993-10: 2010 Biological Evaluation of Medical Devices- Test for Irritation and Skin Sensitization— part 10: Tests for systemic toxicity	The test article identified below was evaluated for intracutaneous reactivity potential on single topical application.	The requirements of the test were met if the difference between the test extract mean score and control mean score was 1.0 or less. 0-No erythema /oedema 1-Slight erythema /oedema 2-Well defined erythema /oedema 3-Moderate erythema /oedema 4-Severe erythema /oedema	Under the conditions of this study, there was no erythema and no edema. The glove is considered a non- irritant.
ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves.	Powder residue limit of 2.0 mg	Requirement met.

ASTM D5151 06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.	This test method covers the detection of holes in medical gloves.	Samples number: 500 gloves AQL: 2.5 (ISO 2859) Criterion ≤ 21 gloves for water leakage	Requirement met.

21. Summary of Clinical Performance Test

No clinical study is included in this submission.

22. Photograph of Powder Free Nitrile Examination Gloves (Indigo)

Product Reference Number: AINPF4X100
('X' on the Product Reference Number denotes the size of the glove, please refer Attachment 15)

23. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device, (K211457: Powder Free Nitrile Examination Gloves, in Indigo is as safe, as effective, and performs as well as or better than the legally marketed predicated device, (K150340: Powder Free Nitrile Examination Gloves in White, Cobalt Blue, Black, and Ice Blue.