August 20, 2021

Careplus (M) SDN BHD
Bee Khoo
Quality Manager
Lot 120 & 121, Jalan Senawang 3, Senawang Industrial Estate
Seremban, 70450 My

Re: K201857
Trade/Device Name: Powder Free Nitrile Examination Glove Black and Dual Color White-Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 8, 2021
Received: July 12, 2021

Dear Bee Khoo:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201857

Device Name
Powder Free Nitrile Examination Glove Black and Dual Color White-Blue

Indications for Use *(Describe)*
A 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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K201857

510(K) SUMMARY

1.0 Applicant: CAREPLUS (M) SDN BHD

Address: Lot 120 & 121 , Jalan Senawang 3,
Senawang Industrial Estate,
70450 Seremban,
Negeri Sembilan Darul Khusus,
Malaysia.

Phone No. 60-6-6772781 Fax No. 60-6-6772780

Contact Person Lim Kwee Shyan

2.0 Date of Summary 18th June, 2021

3.0 Device Information

Device Name **POWDER FREE NITRILE EXAMINATION GLOVE BLACK AND DUAL COLOR WHITE-BLUE**

Common Name : Exam Gloves
Classification Name : Patient Examination Gloves (21 CFR 880.6250, LZA)
Classification Panel : Non-powdered patient examination glove
Class : I

4.0 Predicate Device

Predicate device: Powder Free Nitrile Examination Glove White, 510(k) number K142858 and Powder Free Nitrile Examination Glove Blue, 510(k) number K142862, product code LZA.

5.0 Device Description

Powder Free Nitrile Examination Glove, Black and dual color White-Blue are Class 1 Patient Examination Gloves. The dual color White-Blue is made dual color by double dipping. They are ambidextrous and come in different sizes, Extra Small, Small, Medium, Large and Extra Large, Double Extra-Large and Triple Extra-Large. Gloves meet the ASTM D6319-19 specification below:

Size	XS	S	M	L	XL	XXL	XXXL
Length, min. mm	220		230			NA	
Thickness, min. mm finger palm	0.05 0.05					NA	
Width, ± 10 mm	70	80	95	110	120	NA	

6.0 Indications for Use Statement

A 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.

7.0 Technological Characteristics

Following is a table summarized the technological characteristics compared to Predicate Device and equivalent standards:

Parameter	**Standard Reference**	**Standard Specification**	**Subject Glove (Powder Free Nitrile Examination Glove, Black) K201857**	**Subject Glove (Powder Free Nitrile Examination Glove, Dual Color White-Blue) K201857**	**Predicate Device (Nitrile Blue, K142862 Nitrile White, K142858)**	**Characteristics**
Product Code Regulation number	-	-	LZA 21 CFR 880.6250	LZA 21 CFR 880.6250	LZA 21 CFR 880.6250	Same
Class	-	-	I	I	I	Same
Material	-	-	Nitrile	Nitrile	Nitrile	Same
Color	-	-	Black	White-Blue	Blue, White	Similar
White Pigment	-	-	Titanium Dioxide	Titanium Dioxide	Titanium Dioxide	Same
Size	ASTM D6319-19	-	XS,S,M,L,XL, XXL, XXXL	XS,S,M,L,XL, XXL, XXXL	XS,S,M,L,XL	Similar
Water Tight Test, 1000ml	ASTM D6319-19 ASTM D5151-06	G-I, AQL 2.5	Meets specification	Meets specification	Meets specification	Same
Physical Properties i) Before Ageing Tensile Strength Ultimate Elongation ii) After Ageing ii)Tensile Strength Ultimate Elongation	ASTM D6319-19	 Min. 14 Mpa Min. 500 % Min. 14 Mpa Min. 500	 Meets specification Meets specification	 Meets specification Meets specification	 Meets specification Meets specification	 Same Same
Powder Content	ASTM D6319-19 ASTM D6124-06	Max. 2 mg/glove	Meets specification	Meets specification	Meets specification	Same
Biocompatability Test i) Primary Skin Irritation Test	ISO 10993-10		Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Same
ii) Dermal Sensitization Test	ISO 10993-10		Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.	Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.	Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.	Same
iii) Acute Systemic Toxicity	ISO 10993-11		Conclusion: Under the conditions of this study, the test material both inner and outer surface did not reveal systemic toxicity.	Conclusion: Under the conditions of this study, the test material both inner and outer surface did not reveal systemic toxicity.	Conclusion: Under the conditions of this study, the test material both inner and outer surface did not reveal systemic toxicity.	Same

iv) In vitro Cytotoxicity Test	ISO 10993-5		Conclusions: Under the conditions of this study, the test material is Cytotox(grade >2) at undiluted, 1:2, and Non-cyctotoxic, grade ≤2 at dilutions 1:4, 1:8;1:16,1:32 and 1:64	Conclusions: Under the conditions of this study, the test material is Cytotox(grade >2) at undiluted, 1:2, 1:4, 1:8 and Non-cyctotoxic, grade ≤2 at dilutions;1:16,1:32 and 1:64	White Nitrile: Conclusions: Under the conditions of this study, the test material is Cytotox(grade >2) at undiluted, 1:2, 1:4 and Non-cyctotoxic, grade ≤2 at dilutions; , 1:8 , 1:16,1:32 and 1:64 Blue Nitrile: Conclusions: Under the conditions of this study, the test material is Cytotox(grade >2) at undiluted, 1:2, 1:4, 1:8, 1:16 and Non-cyctotoxic, grade ≤2 at dilutions;1:32 and 1:64	Similar
Single Use	-	-	Single Use	Single Use	Single Use	Same
Labeling	-	-	Single Use	Single Use	Single Use	Same
Intended Use	-	-	A patient examination gloves is a disposal 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 disposal 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 disposal device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same

Parameter	Standard References	Standard Specification	Device Performance		Predicate Device
			Black	White-Blue	
Freedom from pin-holes	ASTM D6319-19	AQL 2.5	1.5 and below	1.5 and below	1.5 and below
Width, mm	ASTM D6319-19	XS – 70 ± 10 S - 80 ± 10 M – 95 ± 10 L – 110 ± 10 XL- 120 ± 10 XXL- NA XXXL- NA	78- 80 86- 88 96- 98 106- 108 116- 118 120- 125 126 -129	78- 80 86- 88 95- 98 107- 108 115- 117 122- 123 129 -132	Meet Specification
Length, mm	ASTM D6319-19	XS - 220 min S - 220 min M – 230 min L – 230 min XL- 230 min XXL- NA XXXL- NA	min. 293 min. 285 min. 287 min. 281 min. 282 min. 292 min. 290	min. 297 min. 285 min. 285 min. 286 min. 301 min. 289 min. 300	Meet Specification
Thickness Palm, mm	ASTM D6319-19	XS – 0.05 min S - 0.05 min M – 0.05 min L – 0.05 min XL- 0.05 min XXL- NA XXXL- NA	min. 0.13 min. 0.15 min. 0.15 min. 0.16 min. 0.15 min. 0.12 min. 0.13	min. 0.15 min. 0.16 min. 0.15 min. 0.15 min. 0.14 min. 0.16 min. 0.14	Meet Specification
Thickness Finger, mm	ASTM D6319-19	XS – 0.05 min S - 0.05 min M – 0.05 min L – 0.05 min XL- 0.05 min XXL- NA XXXL- NA	min. 0.18 min. 0.21 min. 0.21 min. 0.18 min. 0.21 min. 0.16 min. 0.20	min. 0.19 min. 0.20 min. 0.19 min. 0.20 min. 0.20 min. 0.20 min. 0.19	Meet Specification
Tensile Strength Before aging, Mpa	ASTM D6319-19	14 min	min. 25	min. 25	Meet Specification
Tensile Strength After aging, Mpa	ASTM D6319-19	14 min	min. 29	min. 26	Meet Specification
Ultimate Elongation Before aging,%	ASTM D6319-19	500 min	min. 605	min. 606	Meet Specification
Ultimate Elongation After aging,%	ASTM D6319-19	400 min	min. 559	min. 576	Meet Specification
Powder Free Residue	ASTM D6319-19	Max. 2 mg/glove	Max. 1.02	Max. 0.90	Meet Specification

8.0 Summary of Non-Clinical Testing

The performance test data from the non-clinical test met the specifications from ASTM testing methodology.

9.0 Summary of Clinical Testing

Clinical data is not needed for medical gloves or of most devices cleared by the 510(k) process.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.