June 5, 2023

Dell Corning Corporation
% Yiren Qiao
General Manager
Dell Corning Asia Co., Ltd
12E, 7th Floor, Bank of China Tower, Qingshan District
Wuhan, Hubei 430000
China

Re: K230633
Trade/Device Name: APOLLO ADVANTAGE Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: March 3, 2023
Received: March 7, 2023

Dear Yiren Qiao:

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,

Bifeng Qian -S

Bifeng Qian, M.D., 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
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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)*
K230633

Device Name
APOLLO ADVANTAGE Nitrile Examination Gloves

Indications for Use *(Describe)*
APOLLO ADVANTAGE Nitrile Examination Gloves are disposable devices intended for medical purposes that are 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

K230633

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by: Dell Corning Corporation

Address:575 John Dodd Road, Spartanburg, South Carolina 29303, USA.

Contact Person: Yiren Qiao
General Manager

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Date Prepared: May 18, 2023

5.2 Device

Device Name:	APOLLO ADVANTAGE Nitrile Examination Gloves
Classification Name:	Polymer Patient Examination Glove
Regulatory Class:	I
Regulation Number:	21 CFR 880.6250
Regulation Name：	Non-powdered patient examination glove
Product Code:	LZA
Size:	S, M, L, XL

5.3 Predicate Device

Device Name:	Nitrile Examination Glove, K213739
Manufacturer:	Hangzhou Runheng Medical Co., Ltd
Classification Name:	Polymer Patient Examination Glove
Regulatory Class:	I
Regulation Number:	21 CFR 880.6250
Regulation Name：	Non-powdered patient examination glove
Product Code:	LZA
Size:	XS, S, M, L, XL

5.4 Device Description

APOLLO ADVANTAGE Nitrile Examination Gloves are made of Nitrile rubber and are blue in color. The design of proposed device is addressing the standards as ASTM D6124, ASTM D5151 and ASTM D6319. The proposed device is non-sterile and powder free.

5.5 Indication for Use:

APOLLO ADVANTAGE Nitrile Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands to prevent contamination between patient and examiner.

5.6 Comparison of Technological Characteristics

Table 5-1 General Comparison

Item	Proposed Device APOLLO ADVANTAGE Nitrile Examination Gloves	Predicate Device(K213739) Nitrile Examination Glove	Remark
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Classification	I	I	Same
Indication for Use	APOLLO ADVANTAGE Nitrile Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands to prevent contamination between patient and examiner.	Nitrile Examination Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Material	Nitrile	Nitrile	Same
Powered or Powered Free	Powered Free	Powered Free	Same
Color	Blue	Blue	Same

Table 5-2 Device Dimensions Comparison

Proposed Device	Standard	Designation	Size				Tolerance
			S	M	L	XL	
APOLLO ADVANTAGE Nitrile Examination Gloves	ASTM D6319	Length,mm	220	230	230	230	min
		Width, mm	80	95	110	120	±10
		Thickness,mm					
		Finger	0.05				min
		Palm	0.05				min

Predicate Device(K213739) Nitrile Examination Glove ASTM D6319	Standard	Designation	Size					Tolerance
			XS*	S	M	L	XL	
	ASTM D6319	Length,mm	220	220	230	230	230	min
		Width,mm	70	80	95	110	120	±10
		Thickness, mm						
		Finger	0.05					min
		Palm	0.05					min
Remark		Similar *Difference discussion: No size XS is included in our submission. But all sizes we submitted met the specification of ASMT D6319.						

Table 5-3 Performance Comparison

Item			APOLLO ADVANTAGE Nitrile Examination Gloves (**Proposed Device**)	Nitrile Examination Glove(Predicate Device, K213739)	Remark
Colorant			Blue	Blue	Same
Physical Properties	Before Aging Comply with ASTM D6319	Tensile Strength	14MPa,min	14MPa,min	Same
		Ultimate Elongation	500%min	500%min	Same
	After Aging Comply with ASTM D6319	Tensile Strength	14Mpa, min	14Mpa, min	Same
		Ultimate Elongation	400% min	400% min	Same
Freedom from Holes			Free from holes when tested in accordance with ASTM D5151 AQL=2.5	Free from holes when tested in accordance with ASTM D5151 AQL=2.5	Same
Powder Content			0.14mg-0.21mg	≤2mg/glove	Similar

Table 5-4 Biocompatibility Testing Comparison

Item		APOLLO ADVANTAGE Nitrile Examination Gloves (**Proposed Device**)	Nitrile Examination Glove (Predicate Device, K213739)	Remark
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation ISO 10993-10: 2010	The test article has no skin irritation under the conditions of the study.	Not an irritant under the conditions of the study	Same
	Sensitization ISO 10993-10: 2010	The test article showed no evidence of causing delayed dermal contact sensitization under the conditions of the study.	Not a sensitizer under the conditions of the study	Same
	Systemic toxicity ISO 10993-11:2017	The test article showed no evidence of causing acute system toxicity under the conditions of the study.	Device extracts do not pose a systemic toxicity concern under the conditions of the study.	Same

5.7 Non-clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves.

ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

Table 5-5 Summary of non-clinical performance testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length(mm): S:≥220; M/L/XL:≥230;	Length(mm): S:221-238mm; M:232-251mm; L:232-243mm;

		Width(mm): S:80±10; M:95±10; L:110±10; XL:120±10			XL:234-250mm; Width(mm): S:80-89mm; M:94-104mm; L:102-111mm;; XL:111-122mm;
		Thickness(mm): Finger:≥0.05 Palm:≥0.05			Thickness(mm): Finger: S:0.11-0.15mm M:0.11-0.15mm L:0.11-0.14mm XL:0.11-0.16mm Palm: Finger:0.08mm S:0.08mm M:0.08mm L:0.08mm XL:0.08mm
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			0 glove water leakage found
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 <2.0mg			0.14-0.21mg
ASTM D6319	Physical Properties	Before Aging	Tensile Strength	≥14Mpa	34.1-39.0Mpa
			Ultimate Elongation	≥500%	520.808%-637.854%
		After Aging	Tensile Strength	≥14Mpa	32.0-37.0Mpa
			Ultimate Elongation	≥500%	463.000-562.586%
ISO 10993-11	Biocompatibility: Acute Systemic Toxicity	Non-acute systemic toxicity under the conditions of the study.			The test article showed no evidence of causing acute system toxicity under the conditions of the study.
ISO 10993-10	Biocompatibility: Skin Irritation	Non-irritating under the conditions of the study.			The test article has no skin irritation under the conditions of the study.
ISO 10993-10	Biocompatibility: Dermal Sensitization	Non-sensitizing under the conditions of the study.			The test article showed no evidence of causing delayed dermal contact sensitization under the

			conditions of the study.

5.8 Clinical Test Data

Not Applicable

5.9 Conclusion

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicated device Nitrile Examination Glove by Hangzhou Runheng Medical Co., Ltd, cleared under 510(k) K213739.