February 13, 2023
Rhino Health Inc.
% Lisa Capote
Regulatory Counsel
Capote Law Firm
13818 SW 152 Street
Suite 375
Miami, Florida 33177

Re: K223859
Trade/Device Name: Rhino Non-sterile Powder-Free Nitrile Exam Glove - Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: December 12, 2022
Received: December 23, 2022

Dear Lisa Capote:

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
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)* K223859

Device Name
Rhino Non-Sterile, Powder-Free Nitrile Exam Gloves – Periwinkle Color Tested for Use with Chemotherapy Drugs, and Fentanyl.

Indications for Use *(Describe)*

Rhino Non-Sterile Powder-Free Nitrile Exam Gloves - Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The tested chemotherapy drugs are as follows:

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time
Carmustine (BCNU)	(3.3mg/mL 3,300 ppm)	14.2
Cisplatin	(1.0 mg/mL 1,000 ppm)	> 240
Cyclophosphamide (Cytoxan)	(20 mg/mL 20,000 ppm)	> 240
Dacarbazine	(10 mg/mL 10,000 ppm)	> 240
Doxorubicin Hydrochloride	(2.0 mg/mL 2,000 ppm)	> 240
Etoposide (Toposar)	(20.0 mg/mL 20,000 ppm)	> 240
Flurouracil	(50.0 mg/mL 50,000 ppm)	> 240
Paclitaxel (Taxol)	(6.0 mg/mL 6,000 ppm)	> 240
Thiotepa	(10.0 mg/mL 10,000 ppm)	43.2

Fentanyl Tested as Follows:
Fentanyl Citrate Injection (100 mcg/2mL) > 240

Note: Carmustine and Thiotepa have extremely low permeation times of 14.2 and 43.2 minutes respectively.
Warning: Do Not Use with Carmustine, Thiotepa

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

510(K): K223859

Date Prepared: 02/13/2023

I. Submitter:

Company Name:	Rhino Health Inc.
Establishment Reg. No:	3014572471
Address:	309A East, Route 66 Church Rock, New Mexico 87311
Phone Number:	1-833-898-8989
Contact Person:	Mark Lee
Title:	CEO
Phone Number:	1-833-898-8989
Fax Number:	N/A
Email Address:	MLee@RhinoHealth.net

II. Device

Type of 510(k):	Traditional
Proprietary Name:	Rhino Non-sterile Powder-Free Nitrile Exam Glove – Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl
Common Name:	Polymer Patient Examination Glove
Trade Name:	
Classification Name:	Non-Powdered Patient Examination Glove
Review Panel:	General Hospital
Product Code:	LZA, LZC, OPJ, QDO
Regulatory Class:	Class 1, reserved
Regulation Number:	21 CFR 880.6250

III. Predicate Device

Applicant	**Predicate Device**	**510(k) Number**	**Approval Date**
Rhino Health, Inc	Rhino Non-sterile Powder-Free Nitrile Exam Glove – Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanly	K221082	November 30, 2022

IV. Device Description

Rhino Non-sterile Powder-Free Nitrile Exam Glove – Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl are non-sterile, single use, disposable gloves intended for medical purposes to be worn on the hands of examiners to prevent contamination between a patient and an examiner. The gloves are offered in three sizes, extra small, small, and extra large. The color for all sizes is periwinkle. The model number is RHI-UNB5 with specific part sizes based on size as follows:

Glove Size	Part Numbers
XS	RHI-UNB5XS100BX1
S	RHI-UNB5S100BX1
XL	RHI-UNB5XL100BX1

V. Intended Use/Indications for Use:

Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner

Test Results Follow:

Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time**
Carmustine (BCNU)	(3.3mg/mL 3,300 ppm)	14.2
Cisplatin	(1.0 mg/mL 1,000 ppm)	> 240
Cyclophosphamide (Cytoxan)	(20 mg/mL 20,000 ppm)	> 240
Dacarbazine	(10 mg/mL 10,000 ppm)	> 240
Doxorubicin Hydrochloride	(2.0 mg/mL 2,000 ppm)	> 240
Etoposide (Toposar)	(20.0 mg/mL 20,000 ppm)	> 240
Flurouracil	(50.0 mg/mL 50,000 ppm)	> 240
Paclitaxel (Taxol)	(6.0 mg/mL 6,000 ppm)	> 240
Thiotepa	(10.0 mg/mL 10,000 ppm)	43.2
Fentanyl Tested as Follows:		
Fentanyl Citrate Injection	(100 mcg/2mL)	> 240

Note: Carmustine and Thiotepa have extremely low permeation times of 14.2 and 43.2 minutes respectively.
Warning: Do Not Use with Carmustine, Thiotepa

VI. Comparison of Technological Characteristics with Predicate Device

Characteristic	Standard	Subject Device K223859	Predicate Device K221082	Comparison
Device Name & Model:		Non-sterile, Powder-Free Nitrile Exam Glove Model: RHI-UNB5	Non-sterile, Powder-Free Nitrile Exam Glove Model: RHI-UNB5	Identical
510(k) Number:		K223859	K221082	Different
Product Codes:		LZA, LZC, OPJ, QDO	LZA, LZC, OPJ, QDO	Identical
Regulation Number:		21 CFR 880.6250	21 CFR 880.6250	Identical
Regulation Class:		Class I	Class I	Identical
Sterile vs. Non-Sterile:		Non-Sterile	Non-Sterile	Identical
Prescription or OTC:		OTC	OTC	Identical
Single-use Disposable:		Yes	Yes	Identical
Intended Use:	N/A	This device is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	This device is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Identical
Indications for Use:	N/A	Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The tested chemotherapy drugs are as follows: Carmustine (BCNU) (3.3mg/mL 3,300 ppm) 14.2 Cisplatin (1.0 mg/mL 1,000 ppm) > 240 Cyclophosphamide (Cytoxan) (20 mg/mL 20,000 ppm) > 240 Dacarbazine (10 mg/mL 10,000 ppm) > 240 Doxorubicin Hydrochloride (2.0 mg/mL 2,000 ppm) > 240 Etoposide (Toposar) (20.0 mg/mL 20,000 ppm) > 240	Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The tested chemotherapy drugs are as follows: Carmustine (BCNU) (3.3mg/mL 3,300 ppm) 14.2 Cisplatin (1.0 mg/mL 1,000 ppm) > 240 Cyclophosphamide (Cytoxan) (20 mg/mL 20,000 ppm) > 240 Dacarbazine (10 mg/mL 10,000 ppm) > 240 Doxorubicin Hydrochloride (2.0 mg/mL 2,000 ppm) > 240 Etoposide (Toposar) (20.0 mg/mL 20,000 ppm) >	Identical

		Flurouracil (50.0 mg/mL 50,000 ppm) > 240 Paclitaxel (Taxol) (6.0 mg/mL 6,000 ppm) > 240 Thiotepa(10.0 mg/mL 10,000 ppm) 43.2 Fentanyl Tested as Follows: Fentanyl Citrate Injection (100 mcg/2mL) > 240 Note: Carmustine and Thiotepa have extremely low permeation times of 14.2 and 43.2 minutes respectively. Warning: Do Not Use with Carmustine, Thiotepa	240 Flurouracil (50.0 mg/mL 50,000 ppm) > 240 Paclitaxel (Taxol) (6.0 mg/mL 6,000 ppm) > 240 Thiotepa(10.0 mg/mL 10,000 ppm) 43.2 Fentanyl Tested as Follows: Fentanyl Citrate Injection (100 mcg/2mL) > 240 Note: Carmustine and Thiotepa have extremely low permeation times of 14.2 and 43.2 minutes respectively. Warning: Do Not Use with Carmustine, Thiotepa	
Caution/Warning Statements:	N/A	WARNING – Not for use with Carmustine and Thiotepa	WARNING – Not for use with Carmustine and Thiotepa	Identical
Dimensions: Overall Length:	ASTM D6319 Minimum: XS: 220 mm S: 220 mm XL: 230 mm	X-Small: 239 mm Small: 235 mm Medium: N/A Large: N/A X-Large: 237 mm	X-Small: N/A Small: N/A Large: 235 mm Medium: 230 mm X-Large: N/A	Similar
Dimensions: Palm Width (mm):	ASTM D6319 Minimum: XS: 70 ± 10 S: 80 ± 10 M: 95 ± 10 L: 110 ± 10 XL: 120 ± 10	XS: 80 S: 85 M: N/A L: N/A XL: 112	XS: N/A S: N/A M: 90 – 100 L: 103 – 113 XL: N/A	Similar
Dimensions: Palm & Finger Thickness (mm):	ASTM D6319 Minimum Palm: 0.05 Finger: 0.05	XS: Palm: 0.07 mm Finger: 0.11 mm Small: Palm: 0.06 mm Finger: 0.11 mm M: N/A L: N/A XL: Palm: 0.07 mm Finger: 0.11 mm	XS: N/A S: N/A Medium: Palm: 0.07 mm Finger: 0.10 mm Large: Palm: 0.07 mm Finger: 0.10 mm XL: N/A	Similar
Tensile strength: Before & After aging:	ASTM D6319 Min. Before: 14MPa After: 14Mpa	XS: Before: 35.9 MPa After: 38.7 MPa S:	XS: N/A S: N/A Medium: Before: 40.9 MPa	Similar

		Before: 33.7 MPa After: 35.3 MPa M: N/A L: N/A XL: Before: 31.1 MPa After: 34.1 MPa	After: 35.5 MPa Large: Before: 33.4 MPa After: 39.0 MPa XL: N/A	
Ultimate elongation Before & After aging:	ASTM D6319 Minimum: Before: 500% After: 400%	XS: Before: 535% After: 523% S: Before: 535% After: 520% M: N/A L: N/A XL: Before: 535% After: 520%	XS: N/A S: N/A Medium: Before: 550% After: 510% Large: Before: 520% After: 520% XL: N/A	Similar
Freedom from holes:	ASTM D6319 G1, AQL 2.5	Pass XS: No leakers in 50 S: 3 leakers in 100 XL: No leakers in 50	Pass Medium: 2 leakers in 50 3 leakers in 100 Large: 4 leakers in 50 4 leakers in 100 4 leakers in 150	Similar
Powder-Free	ASTM D6319 Maximum <2mg/glove	Pass XS: 1.0 mg S: 0.5 mg M: N/A L: N/A XL: 0.4 mg	Pass XS: N/A S: N/A Medium: 0.9 mg Large: 0.6 mg XL: N/A	Similar
Biocompatibility	ISO 10993-11 Acute Systemic Toxicity Test	Under the conditions of the study, the extracts of the test article did not induce a significantly greater biological reaction than the control extracts. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-11 guidelines.	Under the conditions of the study, the extracts of the test article did not induce a significantly greater biological reaction than the control extracts. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-11 guidelines.	Identical
	ISO 10993-10 Primary Skin Irritation on Rabbits	Under the conditions of the study, the test article sites did not show a significantly greater biological reaction than the sites injected with the control article. The test meets the requirements of ISO 10993-10 guidelines.	Under the conditions of the study, the test article sites did not show a significantly greater biological reaction than the sites injected with the control article. The test meets the requirements of ISO 10993-10 guidelines.	Identical

	ISO 10993-10 Guinea Pig Sensitization	Under the conditions of the study, the extracts of the device elicited no reaction. Therefore, as defined by the grading scale of the USP, the test article is classified as a non-sensitizer. The test article meets the requirements of ISO 10993-10 guidelines.	Under the conditions of the study, the extracts of the device elicited no reaction. Therefore, as defined by the grading scale of the USP, the test article is classified as a non-sensitizer. The test article meets the requirements of ISO 10993-10 guidelines.	Identical

Both devices pass all non-clinical studies. The studies done on both devices are identical. The differences between the Subject Device and Predicate Device do not raise any concerns. The differences include (1) size of the Predicate Device versus the Subject Device; and (2) the results of the various physical tests. The results of the physical tests were different for the Predicate Device and Subject Device, however all results passed in accordance with ASTM D6319, ASTM D6124, and ASTM D5151.

VII. Non-Clinical Studies

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

Test Methodology	**Purpose**	**Acceptance Criteria**			**Results**
ASTM D6319	Physical Dimensions Test	Extra Small: Length: ≥ 220 mm Width: 70 ± 10 mm Small: Length: ≥ 220 mm Width: 80 ± 10 mm Extra Large: Length: ≥ 230 mm Width: 120 ± 10 mm			Pass
		Thickness: Finger: ≥ 0.05 Palm: ≥ 0.05			Pass
	Physical Properties	Before Aging	Tensile Strength	≥ 14 MPa	Pass
			Ultimate Elongation	≥ 500%	Pass
		After Aging	Tensile Strength	≥ 14 MPa	Pass
			Ultimate Elongation	≥ 400%	Pass

ASTM D5151	Freedom from holes	Meet the requirements of ASTM D5151 for AQL 2.5	Pass
ASTM D6124	Powder Residue	< 2.0 mg	Pass
ISO 10993-10	To determine if the finished device material is an irritant	Non-irritating; Primary irritation Index ≤ 1.0	Under the conditions of the study, not an irritant/Pass
ISO 10993-10	To determine if the finished device material is a sensitizer	Non-sensitizing; Grade < 1	Under the conditions of the study, not a sensitizer/Pass
ISO 10993-11	To determine if the finished device material extracts pose a systemic toxicity concern	Non-acute systemic toxicity, no animals treated with test extracts exhibit greater reaction than control animals.	Under the conditions of the study, did not show acute systemic toxicity in vivo/Pass
ASTM D6978-05	To determine permeation rate of specific chemotherapy drugs	The test determines what the permeation of a particular drug is and therefore there is no "acceptance criteria" beyond a minimum breakthrough detection time of >240 min on all three (3) specimens.	All drugs, except Carmustine and Thiotepa, had permeation time of > 20 minutes. Carmustine permeation time was 14.2 minutes and Thiotepa permeation time was 43.2 minutes

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D6978-05(2019), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- 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 - Part11:Tests for Systemic Toxicity

VIII. Clinical Studies

No clinical study is included in this submission.

IX. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Subject Device is as safe, as effective, and performs as well as or better than the legally marketed Predicate Device.