August 16, 2021

Rhino Health Inc
% Lisa Capote
Attorney of Record
Capote Law Firm
13818 SW 152 Street Number 375
Miami, Florida 33177

Re: K203236
Trade/Device Name: Rhino Non-sterile Powder-Free Nitrile Exam Glove – Blue Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: July 15, 2021
Received: November 3, 2020

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,

Jiangsong Jiang -S
(Affiliate)

For Clarence Murray
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)*
K203236

Device Name
Rhino Non-sterile Powder-Free Nitrile Exam Glove – Blue Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
Rhino Non-Sterile Powder-Free Nitrile Patient Exam Glove - Blue 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)	23.1
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)	24.9

Fentanyl Tested as Follows:

Fentanyl Citrate Injection (100mcg/2mL)	> 240

Note: Carmustine and Thiotepa have extremely low permeation times of 23.1 and 24.9minutes respectively.
Warning: Do Not Use with Carmustine and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(K): K203236

Date Prepared: April 28, 2021

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 – Blue Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name:	Polymer Patient Examination Glove
Trade Name:	
Classification Name:	Non-Powdered Patient Examination Glove
Review Panel:	General Hospital
Product Code:	LZA, LZC, QDO
Regulatory Class:	Class 1, reserved
Regulation Number:	21 CFR 880.6250

III. Predicate Device

Applicant	Predicate Device	510(k) Number	Approval Date
Sri Trang Gloves (Thailand) Public Company Limited	Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Lilac, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Orchid, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Oyster	K193581	March 20, 2020

IV. Device Description

The Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Blue 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 Drugs Tested as Follows:		
Carmustine (BCNU)	(3.3mg/mL 3,300 ppm)	23.1
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)	24.9
Fentanyl Opioid Tested as Follows:		
Fentanyl Citrate Injection	(100 mcg/2mL)	> 240

Note: Carmustine and Thiotepa have extremely low permeation times of 23.1 and 24.9minutes respectively.
Warning: Do Not Use with Carmustine and Thiotepa

V. Intended Use:

Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Blue 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)	23.1
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)	24.9
Fentanyl Tested as Follows:		
Fentanyl Citrate Injection	(100 mcg/2mL)	> 240

Note: Carmustine and Thiotepa have extremely low permeation times of 23.1 and 24.9 minutes respectively.
Warning: Do Not Use with Carmustine and Thiotepa

VI. Comparison of Technological Characteristics with Predicate Device

Characteristic	Standard	Subject Device	Predicate Device K193581	Remark
Device Name & Model:		Non-sterile, Powder-Free Nitrile Exam Glove Model: RH001	Non-sterile, Powder- Free Nitrile Exam Glove	Different
510(k) Number:		K203236	K193581	Different
Product Codes:		LZA, LZC, QDO	LZA, LZC, 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
Indications for Use:	N/A	Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Blue 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 Chemotherapy Drug's Concentration at Minimum Breakthrough Detection Time: Carmustine (BCNU)(3.3mg/mL 3,300 ppm) 23.1 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) 24.9 Fentanyl Tested as Follows:Fentanyl Citrate Injection (100 mcg/2mL) > 240	This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Bleomycin Sulfate 15 mg/mL, >240 minutes Busulfan 6 mg/mL, >240 minutes Carboplatin (Paraplatin) 10 mg/mL, >240 minutes Carmustine (BCNU) 3.3 mg/mL, 17.1 minutes Cisplatin 1.0 mg/mL, >240 minutes Cyclophosphamide (Cytoxan) 20 mg/mL, >240 minutes Cytarabine 100 mg/mL, >240 minutes Dacarbazine (DTIC) IO mg/mL, >240 minutes Daunorubicin 5 mg/mL, >240 minutes Docetaxel IO mg/mL, >240 minutes Doxorubicin Hydrochloride 2 mg/mL, >240 minutes Epirubicin (Ellence) 2 mg/mL, >240 minutes Etoposide (Toposar) 20 mg/mL, >240 minutes Fludarabine 25 mg/mL, >240 minutes Fluorouracil 50 mg/mL, >240 minutes	Similar

		Note: Carmustine and Thiotepa have extremely low permeation times of 23.1 and 24.9minutes respectively. Warning: Do Not Use with Carmustine and Thiotepa	Gemcitabine 38 mg/mL, >240 minutes Idarubicin 1 mg/mL, >240 minutes lfosfamide 50 mg/mL, >240 minutes Irinotecan 20 mg/mL, >240 minutes Mechlorethamine I mg/mL, >240 minutes Melphalan 5 mg/mL, >240 minutes Methotrexate 25 mg/mL, >240 minutes Mitomycin C 0.5 mg/mL, >240 minutes Mitoxantrone 2 mg/mL, >240 minutes Paclitaxel (Taxol) 6 mg/mL, >240 minutes Rituximab 10 mg/mL, >240 minutes Thiotepa 10 mg/mL, 27.9 minutes Trisenox 1 mg/mL , >240 minutes Vincristine Sulfate I mg/mL, >240 minutes WARNING: Not for use with Carmustine or Thiotepa. Fentanyl tested as follows: Fentanyl citrate 100 mcg/2mL, >240 minutes	
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: 230 mm Large: 237 mm	238 mm	Similar
Dimensions: Palm Width (mm):	ASTM D6319 Minimum: XS: 70 ± 10 S: 80 ± 10 M: 95 ± 10 L: 110 ± 10 XL: 120 ± 10	M: 90 – 100 L: 103 – 113 N/A	N/A N/A N/A 110 N/A	Similar
Dimensions: Palm & Finger Thickness (mm):	ASTM D6319 Minimum Palm: 0.05 Finger: 0.05	Large: Palm: 0.08 mm Finger: 0.12 mm	Palm: 0.05 mm Finger: 0.08 mm	Similar
Tensile strength: Before & After aging:	ASTM D6319 Min. Before:14MPa After: 14Mpa	Large: Before: 36.8 MPa After: 39.1 MPa	Before: 34 MPa After: 38 MPa	Similar
Ultimate elongation	ASTM D6319	Minimum:	Before: 570%	Similar

Before & After aging:		Before: 500%, After: 400% Large: Before: 540%, After: 490%	After: 535%	
Freedom from holes:	ASTM D6319 G1, AQL 2.5 7 Accept 8 Reject	Medium: No leakers in 50 Large: 1 leaker in 50 2 leakers in 100	Pass	Identical
Powder-Free	ASTM D6319 Maximum <2mg/glove	Pass Medium: 0.1 mg Large: 0.4 mg	Pass	Identical
Biocompatibility	ISO 10993-11 Systemic Toxicity Test	Under the conditions of the study, the extracts of the test article did not induce a significantly greater biological reaction then the control extracts. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-11 guidelines.	The device extracts did not elicit a systemic response in the animal model.	Similar
	ISO 10993-10 Primary Skin Irritatio n 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 article meets the requirements of ISO 10993-10 guidelines.	Under the conditions of the study, the polar and non-polar device extracts were found not to be an irritant to the animal model	Similar
	ISO 10993-10 Guinea Pig Sensitization	Under the conditions of the study, the extracts of the device elicited no reaction. Therefore, as defined b 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 polar and non-polar device extracts were found not to be sensitizers to the animal model.	Similar

For more details, please refer to the Substantial Equivalence Discussion section in this submission.

VII. Summary of Non-clinical Testing

The following performance data was provided to demonstrate the subject device meets the acceptance criteria of the standard shown in the table below:

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D6319	Freedom from holes	AQL 2.5: 8 rejection level	Medium: 0 leakers in 50 Large: 1 leaker in 50 2 leakers in 100

ASTM D6319	Powder-free	Maximum <2mg/glove	Medium: 0.1 mg Large: 0.4 mg
ASTM D6319	Ultimate elongation before and after aging	Minimum Before Aging: 500% After Aging: 400%	Medium: 563% Large: 555% Medium: 528% Large: 500%
ASTM D6319	Tensile Strength before and after aging	Minimum Before: 14 MPa After: 14 MPa	Medium: 44 MPa Large: 38 MPa
ASTM D6319	Palm and Finger Thickness	Minimum: Palm: 0.05 mm Finger: 0.05 mm	Medium: 0.09 mm Large: 0.08 mm
ASTM D6319	Palm Width	Minimum Medium: 95 mm ± 10 Large: 110 mm ± 10	Medium: 93 mm Large: 106 mm
ASTM D6319	Length	Minimum: 230 mm	Medium: 236 mm Large: 243 mm
ASTM D6978	Resistance to Permeation by Chemotherapy Drugs	Permeation time (Minutes): Carmustine (BCNU) (3.3mg/mL 3,300 ppm) > 240 Cisplatin (1.0 mg/mL 1,000 ppm) > 240 Cyclophosphamide (Cytoxan) (20 mg/mL 20,000 ppm) > 240 Dacarbazine (10mg/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	Permeation time (Minutes): Carmustine (BCNU) (3.3mg/mL 3,300 ppm), 23.1 Cisplatin (1.0 mg/mL 1,000ppm) > 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) (20.0mg/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) 24.9

		Thiotepa (10.0 mg/mL 10,000 ppm) > 240 Fentanyl Citrate Injection (100 mcg/2mL) > 240	Fentanyl Citrate Injection (100 mcg/2mL) > 240
ISO 10993-11 Systemic Toxicity Test	Determine the potential toxic effects of the test article extract as a result of a single-dose systemic injection in mice.	Test passes if none of the animals injected show a significantly greater biological reaction than the animals treated with the control article.	The USP 0.9% Sodium Chloride for Injection and Cottonseed Oil extracts of the test article, RHUSA Nitrile glove, did not induce a significantly greater biological reaction than the control extracts following a single dose to Albino Swiss mice. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-11 guidelines.
ISO 10993-10 Primary Skin Irritation on Rabbits	Determine the potential irritation effects of the test article extract as a result of an intracutaneous injection in New Zealand white rabbits	The requirements of the test are met if the difference between the test article mean score and the vehicle control mean score is 1.0 or less.	The over mean score of the test article was 0.4 and the overall mean score of the vehicle control was 0.4.
ISO 10993-10 Guinea Pig Sensitization	Determine the potential allergenic or sensitizing capacity of the test article.	A sensitizer is a test article with which a positive response is observed in at least 10% of the test animals.	0% sensitization observed

1. Biocompatibility:

The biocompatibility evaluation for the body contacting components of Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Blue Tested for Use with Chemotherapy Drugs and Fentanyl was conducted in accordance with ISO 10993-10; Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization and ISO 10993-11; Biological Evaluation of Medical Devices – Part 11: Test for Systemic Toxicity.

2. Performance:

Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Blue Tested for Use with Chemotherapy Drugs and Fentanyl was tested for compliance with ASTM D6319-19; Standard Specification for Nitrile Examination Gloves for Medical Application and ASTM D6978-05; Standard Practice for Assessment of Resistance of Medical Gloves to Permeation

by Chemotherapy Drugs.

VIII. Conclusion

The conclusions drawn from the nonclinical test demonstrate that the Rhino Non-Sterile Powder-Free Nitrile Exam Gloves – Blue Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device.