July 8, 2022

American Nitrile Operations LLC
Stephen Perrin
Manager of Quality Assurance & Regulatory Affairs
3500 Southwest Blvd
Grove City, Ohio 43123

Re: K220825
Trade/Device Name: Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: June 8, 2022
Received: June 13, 2022

Dear Stephen Perrin:

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)*
K220825

Device Name
Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs.

The list of Fentanyl and Chemotherapy Drugs tested (with breakthrough times) are:

Chemotherapy Drug and Concentration	Breakthrough Time (minutes)
Carmustine (BNCU) (3.3 mg/ml)	25.5
Cyclophosphamide (20.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
5-Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	47.7
Vincristine Sulfate (1.0 mg/ml)	>240
Fentanyl (100mcg/2ml)	>240

CAUTION: Testing showed an average breakthrough time of 25.5 min for Carmustine and 47.7 min for 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

K220825

AMERICAN NITRILE OPERATIONS LLC

SAPPHIRE PRO POWDER-FREE ROYAL BLUE NITRILE EXAM GLOVES

510(k) Summary

(In accordance with 21 CFR 807.92)

K220825

Submitter

American Nitrile Operations LLC
3500 Southwest Blvd
Grove City, OH 43123

Contact Person: Stephen R Perrin Jr
Manager of Quality Assurance and Regulatory Affairs
sperrin@americannitrile.com

Summary Preparation Date

08 JUN 2022

Type of 510(k) Submission

Abbreviated

Device Name & Classification	
Trade Name	Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves
Common Name	Non-powdered patient examination glove
Classification Name	Nitrile Blue Chemo and Fentanyl Tested Patient Examination Gloves
Product Code	LZA, LZC, QDO
Review Panel	General Hospital
Regulatory Class	Class I
Regulation Number	21 CFR 880.6250

Predicate Device	
Device Name	Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl)
510k Number	K200150
510k Owner	Medline Industries, Inc.

Device Description:

The Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves 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 nitrile, powder-free, ambidextrous, and blue-colored with a beaded cuff. The range of sizes includes small, medium, large, and extra-large.

Indications for Use:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs.

The list of Chemotherapy Drugs tested (with breakthrough times) are as follows:

Fentanyl and Chemotherapy Drug Permeation Resistance		
Drug Tested	**Concentration**	**Breakthrough Detection Time (minutes)**
Carmustine (BNCU)	3.3 mg/ml	25.5
Cyclophosphamide	20.0 mg/ml	>240
Doxorubicin HCl	2.0 mg/ml	>240
Etoposide	20.0 mg/ml	>240
5-Fluorouracil	50.0 mg/ml	>240
Methotrexate	25.0 mg/ml	>240
Paclitaxel	6.0 mg/ml	>240
Thiotepa	10.0 mg/ml	47.7
Vincristine Sulfate	1.0 mg/ml	>240
Fentanyl Citrate	100mcg/2ml	>240

- CAUTION: Testing showed an average breakthrough time of 25.5 min for Carmustine and 47.7 min for Thiotepa.

Summary of Technological Characteristics

The technological characteristics of the Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves are summarized within the following table comparing subject gloves to the predicate device under ASTM or equivalent standards:

Device Characteristic	Proposed Device K220825	Predicate Device K200150	Comparison Analysis
Product Name	Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves	Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl)	N/A
Product Code	LZA, LZC, QDO	LZA, QDO	Similar
Intended Use	A powder-free patient examination glove is a disposable device intended	A patient examination glove is a disposable device intended for medical purposes	Similar

Device Characteristic	Proposed Device K220825	Predicate Device K200150	Comparison Analysis
	for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs.	that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were Tested for use with Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019)	
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Material Composition	Synthetic Nitrile Rubber	Powder free Nitrile	Same
Color	Blue	Orange	Different
Sizes	Small, Medium, Large, Extra-Large	Small, Medium, Large, Extra-Large, Extra-Extra Large	Similar
Dimensions – Length	Meets Requirements of ASTM D6319-19: 220 mm minimum	Meets Requirements of ASTM D6319-19: 220 mm minimum	Same
Dimensions – Width	Meets Requirements of ASTM D6319-19: 70 mm minimum	Meets Requirements of ASTM D6319-19: 70 mm minimum	Same
Dimensions – Thickness	Meets Requirements of ASTM D6319-19: 0.05 mm minimum (Finger or Palm)	Meets Requirements of ASTM D6319-19: 0.05 mm minimum (Finger and Palm)	Same
Physical Properties – Tensile Strength Physical Properties – Elongation	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa. After Aging ≥14 MPa. Elongation: Before Aging 500%, min. After Aging 400%, min.	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa. After Aging ≥14 MPa. Elongation: Before Aging 500%, min. After Aging 400%, min.	Same
Freedom from Holes	Meets Requirements of ASTM D6319-19 and D5151-19: G-1, AQL 2.5	Meets Requirements of ASTM D6319-19 and D5151-19: G-1, AQL 2.5	Same
Powder or Powder Free	Powder-Free	Powder-Free	Same
Residual Powder	Meets Requirements of ASTM D6319-19 and D6124-06: < 2 mg per glove	Meets Requirements of ASTM D6319-10: < 2 mg per glove	Same
Contact classification	Surface Contacting, less than 24-hour duration	Surface Contacting, less than 24-hour duration	Same
Biocompatibility – Irritation	ISO 10993-10: Under the conditions of the study, not an irritant.	ISO 10993-10: Under the conditions of the study, not an irritant.	Same

Device Characteristic	Proposed Device K220825	Predicate Device K200150	Comparison Analysis
Biocompatibility – Sensitization	ISO 10993-10: Under the conditions of the study, not a sensitizer	ISO 10993-10: Under the conditions of the study, not a sensitizer	Same
Biocompatibility – Cytotoxicity	ISO 10993-5: Under the conditions of the study, 100%, 66.7%, 44.4% specimens were cytotoxic, 29.6%, 19.8% and 13.2% specimens are not cytotoxic	ISO 10993-5: Under the conditions of the study, cytotoxic	Similar
Biocompatibility – Acute Systemic Toxicity	ISO 10993-11: Under the conditions of the study, no evidence of systemic toxicity	ISO 10993-11: Under the conditions of the study, no evidence of systemic toxicity	Same
Chemotherapy Drugs Testing	The following drugs showed no breakthrough at 240 minutes: Cyclophosphamide (20 mg/mL) Doxorubicin HCl (2 mg/mL) Etoposide (20 mg/mL) 5-Fluorouracil (50 mg/mL) Methotrexate (25 mg/mL) Paclitaxel (6 mg/mL) Vincristine Sulfate (1 mg/mL) The following drugs showed breakthrough in less than 60 minutes: Carmustine (3.3 mg/mL) 25.5 minutes Thiotepa (10 mg/mL) 47.7 minutes	None	Expanded efficacy of the proposed device.
Fentanyl Testing	Fentanyl Citrate 100mcg/2ml >240 min.	Fentanyl Citrate 100mcg/2ml >240 min.	Same

Summary of Nonclinical Testing

Non-Clinical Testing was conducted to demonstrate that the Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves met all required design specifications. The test results demonstrated that the proposed device did meet the performance criteria as specified utilizing the following test method standards and specifications:

Name of Test / Standard	Purpose	Acceptance Criteria	Results
ISO 10993-10:2010 (2014)	Irritation	Pass / Fail	Pass – Under the conditions of the study, the subject device is not a primary skin irritant.

Name of Test / Standard	Purpose	Acceptance Criteria	Results
ISO 10993-10:2010 (2014)	Sensitization	Pass / Fail	Pass – Under the conditions of the study, the subject device is not a primary skin sensitizer.
ISO 10993-5:2009 (2014)	Cytotoxicity	Pass / Fail	Fail – Under the conditions of the study, the subject device is cytotoxic.
ISO 10993-11:2017	Acute Systemic Toxicity	Pass / Fail	Pass – Under the conditions of the study, the subject device is not toxic.
ASTM D6319-19 ASTM D3767-03 (2020)	Physical Dimensions	Length: 220 mm min. Width: 70 mm min. Thickness – Palm and Finger: 0.05 mm min.	Pass
ASTM D6978-05 (2019)	Permeation of Fentanyl	240 minutes breakthrough time min.	Pass
ASTM D6978-05 (2019)	Permeation of Chemotherapy Drugs	240 minutes breakthrough time min.	Pass
ASTM D5151-19	Detection of Holes	Leakage detection, AQL 2.5	Pass
ASTM D6124-06 (2017)	Residual Powder	Max 2.0 mg / glove	Pass
ASTM D6319-19 ASTM D412-16 (2021) ASTM D573-04 (2019)	Physical Properties	Tensile Strength: Before Aging ≥ 14 MPa, min After Aging ≥ 14 MPa, min Elongation: Before Aging 500%, min. After Aging 400%, min	Pass

Conclusion

The conclusions drawn from the nonclinical test demonstrates that the device, Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Medline Powder-Free Orange Nitrile Patient Examination Gloves (Tested for use with Fentanyl) – K200150