February 17, 2022

Novid PPE Sdn. Bhd.
Er Chuan
QA Manager
Lot 6071, Jalan Haji Abdul Manan, Batu 5 1/2,
Jalan Meru
Klang, Selangor 41050
Malaysia

Re: K213107
Trade/Device Name: Powder Free Blue 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: September 7, 2021
Received: September 24, 2021

Dear Er Chuan:

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)*

K213107

Device Name
Powder Free Blue Nitrile Examination Gloves

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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K213107

510K Summary

As required by 21 CFR 807.92

1) **Submission Information**:

Date : 18th September 2021
Type of 510(k) Submission : Traditional
Basis for 510(k) Submission : New Device
Applicant : Novid PPE Sdn Bhd
Lot 6071, Jalan Haji Abdul Manan,
Batu 5 ½, Jalan Meru,
41050 Klang, Selangor, Malaysia

Contact Person : Er Chai Chuan (QA Manager)
Lot 6123, Jalan Haji Salleh,
Batu 5 ½, Jalan Meru, 41050 Klang,
Selangor, Malaysia.
E-mail: chuan@notionventure.com
Tel: +6016 3689637

2) Device:

Proprietary Name: Powder Free Blue Nitrile Examination Gloves
Classification Name: Examination Gloves
Regulation Number: 880.6250
Product Code: LZA
Device Class: I
Review Panel: General Hospital

3) Device Description

The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical properties. ASTM conforming tensile properties create a glove that is strong and flexible. The glove is manufactured in accordance with the requirements of ASTM D6319 and ASTM D5151. This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between patient and examiner.

4) Identification of the Legally Marketed Devices

Class 1 Nitrile Patient Examination Gloves LZA, powder free that meets all the requirements of ASTM standard D6319 and FDA water leak test.

5) The Intended Use of Gloves

A Nitrile Examination Glove is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Comparison of Technological Characteristics with the Predicate Device:

Table 1: General Comparison

Technological characteristics Comparison to Predicate Device			
	Subject Device Novid PPE Sdn Bhd's Powder Free Blue Nitrile Examination Gloves	**Predicate Device** Mercator Medical (Thailand) LTD's mCare Powder Free Nitrile Blue Examination Gloves -	**Comparison**
510K Number	**K213107**	**K172930**	
Indications for Use	The device 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	The device is a disposable device intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Design Specification	Meet ASTM D6319-10	Meet ASTM D6319-10	Same
Performance Physical Properties	Meet ASTM D6319-10	Meet ASTM D6319-10	Same
Material of Composition	Synthetic Nitrile Rubber	Synthetic Nitrile Rubber	Same
Biocompatibility: Animal Irritation Test Rabbit	Under the condition of study, not an irritant	Under the condition of study, not an irritant	Same
Dermal Sensitization Test- Guinea Pig	Under the condition of study, not a sensitizer	Under the condition of study, not a sensitizer	Same
Acute Systemic Cytotoxicity	Under the condition of the study, no adverse biological reaction	Under the condition of the study, no adverse biological reaction	Same
Color	Synthetic gloves with embedded colorant-Blue	Synthetic gloves with embedded colorant-Blue	Same
Sterility	Non-Sterile	Non-Sterile	Same

Powder Free	Meets applicable definition for Powder free; ≤ 2mg per glove	Meets applicable definition for Powder free; ≤ 2mg per glove	Same
Labelling Information	Single Use indication, Powder free, device name, gloves size, quantity, Patient examination gloves, Non-sterile	Single Use indication, Powder free, device name, gloves size, quantity, Patient examination gloves, Non-sterile	Same
Physical Properties as per ASTM D6319-10	**Before Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 400%	**Before Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 MPa Ultimate Elongation Min 400%	Same
Dimension as per ASTM D6319-10	Finger Thickness: 0.06 – 0.10 mm Length: min 230 mm	Finger Thickness: Min 0.05 mm Length: min 230 mm	Similar
Freedom from holes	AQL per CFR 21.800.20 Test as per ASTM D5151	AQL per CFR 21.800.20 Test as per ASTM D5151	Same
Residual Powder	Tested to ASTM D6124 and meets requirement	Tested to ASTM D6124 and meets requirement	Same

6) Non-clinical test was performed on the proposed device:

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:

a) ISO 10993-10:2010 – Biological evaluation of medical devices- Part 10: Tests for Irritation and Skin Sensitization
b) ISO 10993-11- Biological Evaluation of Medical devices- Part 11: Tests for Systemic toxicity
c) ASTM D6124-06 (Reapproved 2017), Standard test method for Residual powder on medical gloves
d) ASTM D5151-06 (Reapproved 2015), Standard Test Method for Detection of Holes in medical gloves
e) ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application

Performance data of gloves based on ASTM D6977 and FDA Watertight Test

In addition the proposed device was tested and conformed to the following standards and requirements stated in guidance for industry passed and FDA staff - Premarket Notification [510(k)] Submission issued on March 5, 2004:

Table 2: Performance Testing Performance data of gloves and Biocompatibility Testing based on animal studies, biocompatibility studies i) Skin irritation in rabbits, Guinea pig sensitization (Buehler) and acute systemic cytotoxicity test were conducted on Novid PPE Sdn Bhd's final and finished Powder Free Blue Nitrile Examination Gloves.

Test Method	Purpose	Acceptance Criteria	Powder Free Blue Nitrile Examination Gloves Results
ASTM D 5151	Pinhole Test	Free from holes, AQL 1.5	Pass
ASTM D6319	Physical Properties	Before Aging Tensile Strength: Min 14 MPa Elongation: Min 500% After Aging Tensile Strength: Min 14 MPa Elongation: Min 400%	Pass

1. Watertight (1000mL) in accordance with ASTM D5151	Leak Test	Single Sampling in accordance with ISO 2859 **G1 : AQL 2.5**	Pass G1 : AQL 2.5
2. Length (mm) Size S M L XL	Physical Properties	 Min 220 Min 230 Min 230 Min 230	 240mm minimum for all sizes
3. Palm width (mm) Size S M L XL	Physical Properties	 80 ± 10 95 ± 10 110 ± 10 120 ± 10	 84 – 86 95-96 108 – 109 114 - 115
4. Thickness (mm) Single Layer Finger Palm Cuff	Physical Properties	 Min 0.05 Min 0.05 Min 0.05	 Min 0.06 Min 0.06 Min 0.05

5. Physical Properties in accordance with ASTM D412 **Before Aging** Tensile Strength (MPa) Ultimate Elongation (%) **After Aging** Tensile Strength (MPa) Ultimate Elongation (%)	Physical Properties	 Min 14 Min 500 Min 14 Min 400	 17 – 23 540 – 607 21 – 27 480 - 565
6. Powder Content in accordance with ASTM D6124	Powder Residue	Max 2.0 mg/ glove	Below 2.0 mg/ glove
I. Guinea Pig Sensitization	This test was designed to determine if the test article is a potential sensitizer to guinea pigs when applied atopically.	No deviations were noted, observed nor require clarification.	No reaction was observed upon removal of the test material and there was no positive allergic reaction observed on the test of guinea pigs during the challenge phase. None of the guinea pigs was sensitized. Conclusion: meets conformance requirements
II. Primary Dermal	This test was designed to	No deviations were noted, observe nor	Each test was individually

	Irritation in Rabbits	identify substances which are primary irritants to rabbit skin	require clarification.	examined and scored at 24 ± 2, 48 ± 2 and 72 ± 2 hours for erythema and edema using the Draize skin scoring scale. Results obtained as Primary Irritation Index was 0. Conclusion: meets conformance requirements.
III.	Acute Systemic Cytotoxicity in Rats	This test was designed to identify any adverse biological reaction following administration of the extracts of the test item on the rats.	No adverse reaction was noted, observed nor require clarification.	For the 4 days observation done on the test subject by doing: 1) Cage- side observation- all animals survived and appeared healthy and active through out of 4 days. 2) Body weight- all animals gained body weight through out of the 4 days.

			3) Pathology- At sacrifice times, gross necropsies showed no abnormalities for any of the animals. Conclusion: meets conformance requirements.

7) Clinical Test Conclusion
No clinical study is included in this submission

8) Conclusion
The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and perform as well as or better than the legally marketed predicated K172930.