November 11, 2022

Hartalega NGC Sdn. Bhd.
Nurul Kong
General Manager-Quality Assurance
No. 1, Persiaran Tanjung
Kawasan Perindustrian Tanjung
Sepang, Selangor Darul Ehsan 43900
Malaysia

Re: K222225
Trade/Device Name: Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: August 9, 2022
Received: August 17, 2022

Dear Nurul Kong:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222225

Device Name

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue)

Indications for Use *(Describe)*

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs.

These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	10.2
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	30.2
Vincristine Sulfate (1.0 mg/ml)	>240
Bleomycin Sulfate, 15.0 mg/ml	>240
Bortezomib, 1.0 mg/ml	>240
Busulfan, 6.0 mg/ml	>240
Carboplatin, 10.0 mg/ml	>240
Chloroquine, 50.0 mg/ml	>240
Cyclosporin A, 100.0 mg/ml	>240
Cytarabine, 100.0 mg/ml	>240
Daunorubicin, 5.0 mg/ml	>240
Docetaxel, 10.0 mg/ml	>240
Epirubicin, 2.0 mg/ml	>240
Fludarabine, 25.0 mg/ml	>240
Gemcitabine, 38.0 mg/ml	>240
Idarubicin, 1.0 mg/ml	>240
Ifosfamide, 50.0 mg/ml	>240
Irinotecan, 20.0 mg/ml	>240
Mechlorethamine HCI, 1.0 mg/ml	>240
Melphalan, 5.0 mg/ml	>240
Mitoxantrone, 2.0 mg/ml	>240
Oxaliplatin, 2.0 mg/ml	>240
Paraplatin, 10.0 mg/ml	>240
Retrovir, 10.0 mg/ml	>240
Rituximab, 10.0 mg/ml	>240
Topotecan, 1.0 mg/ml	>240

Trisenox, 1.0 mg/ml	> 240

Caution: Testing showed an average breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa.
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

K222225

NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS (BLUE)

(The information contained herein is being provided in accordance with the requirements of 21 CFR 807.92)

1. SUBMISSION APPLICANT

Date Prepared	:	November 10, 2022
Name	:	Hartalega NGC Sdn. Bhd.
Address	:	No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor, Malaysia
Establishment Registration Number	:	3011200663

SUBMISSION CORRESPONDENT AND/OR PREPARER

Contact Name	:	Nurul Aisyah Kong
Contact Title	:	General Manager – Quality Assurance
Phone Number	:	(603) 3280 3888
Fax Number	:	(603) 3271 0135
Contact Email	:	wkkong@hartalega.com.my

2. DEVICE IDENTIFICATION

Common Name of the Device	:	Examination Glove
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue)
Device Class	:	1
Product Code	:	LZA, LZC, OPJ
Regulation Number	:	21 CFR 880.6250

3. PREDICATE DEVICE INFORMATION

510(k) Number	Tradename	Product Code
K151997	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs – Violet Blue (VBLU)	LZA

Regulation Name	:	Patient Examination Glove
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs – Violet Blue (VBLU)
Device Class	:	1
Product Code	:	LZA
Regulation Number	:	21 CFR 880.6250

4. DESCRIPTION OF THE DEVICE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue) is a disposable single-use, non- sterile, blue-colored and powder-free examination glove made from nitrile latex.

5. INDICATIONS FOR USE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs.

The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	10.2
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (20.0 mg/ml)	> 240
Dacarbazine (10.0 mg/ml)	> 240
Doxorubicin Hydrochloride (2.0 mg/ml)	> 240
Etoposide (20.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Methotrexate (25.0 mg/ml)	> 240
Mitomycin C (0.5 mg/ml)	> 240
Paclitaxel (6.0 mg/ml)	> 240

Thiotepa (10.0 mg/ml)	30.2
Vincristine Sulfate (1.0 mg/ml)	> 240
Bleomycin Sulfate, 15.0 mg/ml	> 240
Bortezomib, 1.0 mg/ml	> 240
Busulfan, 6.0 mg/ml	> 240
Carboplatin, 10.0 mg/ml	> 240
Chloroquine, 50.0 mg/ml	> 240
Cyclosporin A, 100.0 mg/ml	> 240
Cytarabine, 100.0 mg/ml	> 240
Daunorubicin, 5.0 mg/ml	> 240
Docetaxel, 10.0 mg/ml	> 240
Epirubicin, 2.0 mg/ml	> 240
Fludarabine, 25.0 mg/ml	> 240
Gemcitabine, 38.0 mg/ml	> 240
Idarubicin, 1.0 mg/ml	> 240
Ifosfamide, 50.0 mg/ml	> 240
Irinotecan, 20.0 mg/ml	> 240
Mechlorethamine HCl, 1.0 mg/ml	> 240
Melphalan, 5.0 mg/ml	> 240
Mitoxantrone, 2.0 mg/ml	> 240
Oxaliplatin, 2.0 mg/ml	> 240
Paraplatin, 10.0 mg/ml	> 240
Retrovir, 10.0 mg/ml	> 240
Rituximab, 10.0 mg/ml	> 240
Topotecan, 1.0 mg/ml	> 240
Trisenox, 1.0 mg/ml	> 240

Caution: Testing showed an average breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa.
Warning: Do not use with Carmustine and Thiotepa

6. TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

Characteristics and Parameters	Subject Device	Predicate Device (K151997)	Discussion
Trade Name	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue)	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue (VBLU)	-
Applicant	Hartalega NGC Sdn. Bhd.	Hartalega NGC Sdn. Bhd.	Same
Product Code	LZA, LZC, OPJ	LZA	Similar
Classification	1	1	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same

Regulation Name	Patient Examination Glove	Patient Examination Glove	Same
Indications for Use	A non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs. The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. **Chemotherapy Drug and Concentration** / **Minimum Breakthrough Detection Time in Minutes** Carmustine, 3.3 mg/ml 10.2 Cisplatin, 1.0 mg/ml > 240 Cyclophosphamide (Cytoxan), 20.0 mg/ml > 240 Dacarbazine, 10.0 mg/ml > 240 Doxorubicin Hydrochloride, 2.0 mg/ml > 240 Etoposide (Toposar), 20.0 mg/ml > 240 Fluorouracil, 50.0 mg/ml > 240 Methotrexate, 25.0 mg/ml > 240 Mitomycin C, 0.5 mg/ml > 240 Paclitaxel (Taxol), 6.0 mg/ml > 240 Thiotepa, 10.0 mg/ml 30.2 Vincristine Sulfate, 1.0 mg/ml > 240 Bleomycin Sulfate, 15.0 mg/ml > 240 Bortezomib, 1.0 mg/ml > 240 Busulfan, 6.0 mg/ml > 240 Carboplatin, 10.0 mg/ml > 240 Chloroquine, 50.0 mg/ml > 240 Cyclosporin A, 100.0 mg/ml > 240 Cytarabine, 100.0 mg/ml > 240 Daunorubicin, 5.0 mg/ml > 240 Docetaxel, 10.0 mg/ml > 240 Epirubicin, 2.0 mg/ml > 240 Fludarabine, 25.0 mg/ml > 240 Gemcitabine, 38.0 mg/ml > 240 Idarubicin, 1.0 mg/ml > 240 Ifosfamide, 50.0 mg/ml > 240 Irinotecan, 20.0 mg/ml > 240 Mechlorethamine HCl, 1.0 mg/ml > 240	A non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs. The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. **Chemotherapy Drug and Concentration** / **Minimum Breakthrough Detection Time in Minutes** Carmustine, 3.3 mg/ml 10.2 Cisplatin, 1.0 mg/ml > 240 Cyclophosphamide (Cytoxan), 20.0 mg/ml > 240 Dacarbazine, 10.0 mg/ml > 240 Doxorubicin Hydrochloride, 2.0 mg/ml > 240 Etoposide (Toposar), 20.0 mg/ml > 240 Fluorouracil, 50.0 mg/ml > 240 Methotrexate, 25.0 mg/ml > 240 Mitomycin C, 0.5 mg/ml > 240 Paclitaxel (Taxol), 6.0 mg/ml > 240 Thiotepa, 10.0 mg/ml 30.2 Vincristine Sulfate, 1.0 mg/ml > 240 **Caution:** Testing showed an average breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa. **Warning:** Do not use with Carmustine and Thiotepa	Similar

	Melphalan, 5.0 mg/ml > 240 Mitoxantrone, 2.0 mg/ml > 240 Oxaliplatin, 2.0 mg/ml > 240 Paraplatin, 10.0 mg/ml > 240 Retrovir, 10.0 mg/ml > 240 Rituximab, 10.0 mg/ml > 240 Topotecan, 1.0 mg/ml > 240 Trisenox, 1.0 mg/ml > 240 **Caution:** Testing showed an average breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa. **Warning:** Do not use with Carmustine and Thiotepa		
Type of use	Over the counter use	Over the counter use	Same
Materials	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
Design	• Single Use • Non-sterile • Powder-Free • Ambidextrous	• Single Use • Non-sterile • Powder-Free • Ambidextrous	Same
Sterility	Non-sterile	Non-sterile	Same
Freedom from holes	Meets ASTM D5151-19 and ASTM D6319-19: AQL 1.5	Meets ASTM D5151-19 and ASTM D6319-19: AQL 1.5	Same
Length	Meets ASTM D6319-19: ≥ 230 mm	Meets ASTM D6319-19: ≥ 240 mm	Same
Dimensions	Meets ASTM D6319-19: XS - 70 ± 10 mm S - 80 ± 10 mm M - 95 ± 10 mm L - 110 ± 10 mm XL - 120 ± 10 mm	Meets ASTM D6319-19: XS - 70 ± 10 mm S - 80 ± 10 mm M - 95 ± 10 mm L - 110 ± 10 mm XL - 120 ± 10 mm	Same
Thickness	Meets ASTM D6319-19: Palm Thickness: Min 0.05 mm Finger Thickness: Min 0.05 mm	Meets ASTM D6319-19: Palm Thickness: 0.08 ± 0.01 mm Finger Thickness: ≥ 0.10 mm	Same
Physical Properties	Meets ASTM D6319-19: Tensile Strength Before Aging: ≥ 14 MPa Tensile Strength After Aging: ≥ 14 MPa Ultimate Elongation Before Aging: ≥ 500 % Ultimate Elongation After Aging: ≥ 400 %	Meets ASTM D6319-19: Tensile Strength Before Aging: ≥ 14 MPa Tensile Strength After Aging: ≥ 14 MPa Ultimate Elongation Before Aging: ≥ 500 % Ultimate Elongation After Aging: ≥ 400 %	Same
Powder residual	Meets ASTM D6319-19 & ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Meets ASTM D6319-19 & ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Same
Primary Skin Irritation ISO 10993-10	Under the conditions of the study, the device is not an irritant	Under the conditions of the study, the device not an irritant	Same
Dermal	Under the conditions of the study, the	Under the conditions of the study, the	Same

Sensitization ISO 10993-10	device is not a sensitizer	device not a sensitizer	
Acute Systemic Toxicity Test ISO 10993-11 (2017)	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Not performed	Different

7. SUMMARY OF NON-CLINICAL TESTING:

Non-clinical tests were conducted to verify that the subject device meets all design specifications.

Test	Purpose	Criteria	Result
Standard Test Method for Detection of Holes in Medical Gloves ASTM D5151-19	To demonstrate glove integrity	Freedom from holes AQL 1.5%	Pass
Standard Test Method for Residual Powder on Medical Gloves ASTM D6124-06(R17)	To demonstrate the gloves are 'powder free'	Average less than 2 mg/glove	Pass
Dimensional Conformance ASTM D6319	To demonstrate appropriate dimensions for labeled sizes	Conforms to ASTM D6319 width, thickness, and length requirements for XS, S, M, L, and XL AQL 4%	Pass
Tensile Performance ASTM D6319	To demonstrate adequate tensile properties	Conforms to ASTM D6319 tensile strength of at least 14MPa and ultimate elongation of at least 500% requirements prior to aging, and tensile strength of at least 14MPa and ultimate strength of at least 400% after accelerated aging AQL 4%	Pass
Biocompatibility: Skin Irritation ISO 10993-10	To demonstrate low potential for skin irritation	Under the conditions of the study, not an irritant.	Pass
Biocompatibility: Skin Sensitization ISO 10993-10	To demonstrate low potential for skin sensitization	Under the conditions of the study, not a sensitizer	Pass
Biocompatibility: Acute Toxicity ISO 10993-11	To demonstrate low acute toxicity	Under the conditions of the study, no acute toxicity.	Pass

CLINICAL PERFORMANCE DATA:

Not applicable. No clinical testing was performed in support of this submission.

CONCLUSION:

The conclusions drawn from the non-clinical performance data demonstrate that, the subject device, Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue), is as safe, as effective and performs as well as or better than the legally marketed predicate device K151997.