January 8, 2025

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

Re: K243818
Trade/Device Name: Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: November 29, 2024
Received: December 12, 2024

Dear Nurul Aisyah 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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)*
K243818

Device Name
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)

Indications for Use *(Describe)*
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (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 and Fentanyl Citrate.

These gloves were tested for use with chemotherapy drugs and fentanyl citrate as per ASTM 06978-05 (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 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, 1u.u 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

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100mcg/2ml	>240

Caution: Testing showed a minimum 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.

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K243818

SPECIAL 510(k) SUMMARY

FOR

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

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

SUBMISSION APPLICANT

Date Prepared	:	January 6, 2025
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

DEVICE IDENTIFICATION

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

PREDICATE DEVICE INFORMATION

510(k) Number	:	K222225
Manufacturer	:	Hartalega NGC Sdn. Bhd.
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue)
Device Class	:	1
Product Code	:	LZA, LZC

DESCRIPTION OF THE DEVICE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) is a disposable single-use, non- sterile, blue-colored and powder-free examination glove made from nitrile latex. Gloves meet the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs and fentanyl citrate as per ASTM D6978-05(2019).

DEVICE MODIFICATION:

The proposed modification to the predicate device is the inclusion of the claim that the subject device has been tested for use with fentanyl citrate in addition to its existing claim of use with chemotherapy drugs. The proposed device (physically identical to the predicate device) was tested for use with fentanyl citrate as per ASTM D6978. There are no differences with these two gloves in materials, manufacturing process and compliance with ASTM D6319 performance specifications.

INDICATIONS FOR USE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (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 and Fentanyl Citrate.

The gloves were tested for use with chemotherapy drugs and fentanyl citrate 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 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 a minimum breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa.

Warning: Do not use with Carmustine and Thiotepa

Fentanyl Citrate and Concentration	**Minimum Breakthrough Detection Time in Minutes**
Fentanyl Citrate Injection, 100 mcg/2ml	> 240

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device</th><th>Predicate Device (K222225)</th><th>Discussion</th></tr>
<tr><td>Trade Name</td><td>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)</td><td>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue)</td><td>Similar</td></tr>
<tr><td>Applicant</td><td>Hartalega NGC Sdn. Bhd.</td><td>Hartalega NGC Sdn. Bhd.</td><td>Same</td></tr>
<tr><td>Product Code</td><td>LZA, LZC, QDO, OPJ</td><td>LZA, LZC</td><td>Similar</td></tr>
<tr><td>Classification</td><td>1</td><td>1</td><td>Same</td></tr>
<tr><td>Regulation Number</td><td>21 CFR 880.6250</td><td>21 CFR 880.6250</td><td>Same</td></tr>
<tr><td>Regulation Name</td><td>Patient Examination Glove</td><td>Patient Examination Glove</td><td>Same</td></tr>
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The gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.</td><td>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.</td><td>Similar</td></tr>
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</table>
</td><td>Tested chemotherapy drugs: Same</td></tr>
</table>

Characteristics and Parameters	Subject Device	Predicate Device (K222225)	Discussion
	Rituximab, 10.0 mg/ml > 240 Topotecan, 1.0 mg/ml > 240 Trisenox, 1.0 mg/ml > 240 **Caution:** Testing showed a minimum breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa. **Warning:** Do not use with Carmustine and Thiotepa	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	
	Fentanyl Citrate and Concentration / **Minimum Breakthrough Detection Time in Minutes** Fentanyl Citrate, 100.0 mcg/2ml / > 240	N/A	Fentanyl Citrate was tested on subject device: Different
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: ≥ 230 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: Min 0.05 mm Finger Thickness: Min 0.05 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 is not an irritant	Same
Dermal Sensitization ISO 10993-10	Under the conditions of the study, the device is not a sensitizer	Under the conditions of the study, the device is not a sensitizer	Same

Characteristics and Parameters	Subject Device	Predicate Device (K222225)	Discussion
Acute Systemic Toxicity Test ISO 10993-11	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Same

The subject device and the predicate device are identical. However, the subject device has been tested for use with both chemotherapy drugs and fentanyl citrate, whereas the predicate device has only been tested for use with chemotherapy drugs.

SUMMARY OF NON-CLINICAL TESTING:

The subject device and the predicate device share the same intended use, identical material and identical manufacturing, and therefore share the same chemotherapy drug permeation testing, biocompatibility characteristics and compliance with ASTM D6319. Fentanyl citrate permeation testing was performed on the subject glove using the ASTM D6978 method

Testing Performed	Purpose	Criteria	Result
ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Demonstrate barrier properties of gloves to permeation of Fentanyl Citrate solution	N/A	No breakthrough detected during 240 minute test duration

The following testing was previously performed on the physically-identical predicate device.

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

ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Demonstrate barrier properties of gloves to permeation of chemotherapy drugs: Carmustine (3.3 mg/ml) Cisplatin (1.0 mg/ml) Cyclophosphamide (20.0 mg/ml) Dacarbazine (10.0 mg/ml) Doxorubicin Hydrochloride (2.0 mg/ml) Etoposide (20.0 mg/ml) Fluorouracil (50.0 mg/ml) Methotrexate (25.0 mg/ml) Mitomycin C (0.5 mg/ml) Paclitaxel (6.0 mg/ml) Thiotepa (10.0 mg/ml) Vincristine Sulfate (1.0 mg/ml) Bleomycin Sulfate, 15.0 mg/ml Bortezomib, 1.0 mg/ml Busulfan, 6.0 mg/ml Carboplatin, 10.0 mg/ml Chloroquine, 50.0 mg/ml Cyclosporin A, 100.0 mg/ml Cytarabine, 100.0 mg/ml Daunorubicin, 5.0 mg/ml Docetaxel, 10.0 mg/ml Epirubicin, 2.0 mg/ml Fludarabine, 25.0 mg/ml Gemcitabine, 38.0 mg/ml Idarubicin, 1.0 mg/ml Ifosfamide, 50.0 mg/ml Irinotecan, 20.0 mg/ml Mechlorethamine HCI, 1.0 mg/ml Melphalan, 5.0 mg/ml Mitoxantrone, 2.0 mg/ml Oxaliplatin, 2.0 mg/ml Paraplatin, 10.0 mg/ml Retrovir, 10.0 mg/ml Rituximab, 10.0 mg/ml Topotecan, 1.0 mg/ml Trisenox, 1.0 mg/ml	N/A	Carmustine Minimum breakthrough time: 10.2 minutes ThioTepa Minimum breakthrough time: 30.2 minutes No breakthrough detected during 240 minute test duration for remaining tested chemotherapy drugs

CLINICAL PERFORMANCE DATA:

Not applicable.

CONCLUSION:

The conclusions drawn from the non-clinical testing demonstrates that the subject device, Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue), is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue) K222225.