January 19, 2022

Showa Best Glove, Inc.
Jeffrey Richardson
Director of Operations
579 Edison Street
Menlo, Georgia 30731

Re: K211003
Trade/Device Name: SHOWA® Blue Nitrile Powder Free Medical Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: December 8, 2021
Received: December 9, 2021

Dear Jeffrey Richardson:

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)*
K211003

Device Name
SHOWA®Blue Nitrile Powder Free Medical Examination Glove

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by chemotherapy drugs.

Chemotherapy Drugs and Concentration	Minimum breakthrough detection time (Min) µg/cm²/min
Chemotherapy Drug and concentration	Minimum Breakthrough, detection time in minutes, minutes
1) Blenoxane (15.0 mg/ml) 15,000 ppm	>240 minutes
2) Busulfan (6.0 mg/ml) 6,000 ppm	>240 minutes
3) Carboplatin (10.0 mg/ml) 10,000 ppm	>240 minutes
4) Carmustine (3.3 mg/ml) 3,300 ppm	73.7 minutes
5) Cisplatin (1.0 mg/ml) 1,000 ppm	>240 minutes
6) Cyclophosphamide (20.0 mg/ml) 20,000 ppm	>240 minutes
7) Cytarabine (100.0 mg/ml) 100,000 ppm	>240 minutes
8) Dacarbazine (10.0 mg/ml) 10,000 ppm	>240 minutes
9) Daunorubicin HCl (5.0 mg/ml) 5,000 ppm	>240 minutes
10) Docetaxel (10.0 mg/ml) 10,000 ppm	>240 minutes
11) Doxorubicin HCl (2.0 mg/ml) 2,000 ppm	>240 minutes
12) Epirubicin HCl (2.0 mg/ml) 2,000 ppm	>240 minutes
13) Etoposide (20.0 mg/ml) 20,000 ppm	>240 minutes
14) Fludarabine (25.0 mg/ml) 25,000 ppm	>240 minutes
15) Fluorouracil (50.0 mg/ml 50,000 ppm	>240 minutes
16) Gemcitabine (38.0 mg/ml) 38,000 ppm	>240 minutes
17) Idarubicin HCl (1.0 mg/ml) 1,000 ppm	>240 minutes
18) Ifosfamide (50.0 mg/ml) 50,000 ppm	>240 minutes
19) Irinotecan (20.0 mg/ml) 20,000 ppm	>240 minutes
20) Mechlorethamine HCl (1.0 mg/ml) 1,000 ppm	>240 minutes
21) Melphalan (5.0 mg/ml) 5,000 ppm	>240 minutes
22) Methotrexate (25.0 mg/ml) 25,000 ppm	>240 minutes
23) Mitomycin C (0.5 mg/ml) 500 ppm	>240 minutes
24) Mitoxantrone (2.0 mg/ml) 2,000 ppm	>240 minutes
25) Paclitaxel (6.0 mg/ml) 6,000 ppm	>240 minutes
26) Rituximab (10.0 mg/ml) 10,000 ppm	>240 minutes
27) ThioTepa (10.0 mg/ml)10,000 ppm	25.4 minutes
28) Trisenox (1.0 mg/ml) 1,000 ppm	>240 minutes
29) Vincristine Sulfate (1.0 mg/ml) 1,000 ppm	>240 minutes

The maximum testing time is 240 minutes.
Warning: Do not use with Carmustine or 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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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
K211003
DATE OF PREPARATION: January 14, 2022

I. SUBMITTER

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Menlo, GA 30731
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Fax: 706-862-6000

II. OFFICIAL CORRESPONDENCE/CONTACT PERSON

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III. 510(K) PREPARER

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Fax: 706-862-2660
Email: Bmoseley@showagroup.com

IV. PROPOSED DEVICE

Trade Name/Proprietary Name: SHOWA® Blue Nitrile Powder Free Medical Examination Glove
Common or Usual Name: Nitrile Patient Examination Glove
Classification Name: Patient Examination Glove
Regulation: 21 CFR 880.6250
Device Classification: Class: I
Product Code: LZA, LZC

V. PREDICATE DEVICE

Device Classification Name: Polymer Patient Examination Glove
510(k) Number: K200581
Product Code: LZA, LZC
Applicant: Hartelega NGC SDN.BHD.
Kawasan Perindustrian Tanjung
Sepang, MY 43900

VI. DEVICE DESCRIPTION

The SHOWA® Blue Nitrile Powder Free Medical Examination Glove is a single use, disposable device made from a Nitrile Butadiene Rubber, blue in color, powder free and non-sterile (per 21 CFR Part 880.6250, class I). The device meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility and permeability to chemotherapy drugs.

The SHOWA® Blue Nitrile Powder Free Medical Examination Glove is designed to be used for medical purposes to be worn on the examiner's hands or fingers to prevent contamination between the patient and the examiner (product code LZA). In addition, these gloves were tested for use with chemotherapy drugs (product code LZC) in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by chemotherapy drugs.

VII. INDICATIONS FOR USE

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by chemotherapy drugs.

Chemotherapy Drug and concentration	**Minimum Breakthrough, detection time in minutes, minutes**
1) Blenoxane (15.0 mg/ml) 15,000 ppm	>240
2) Busulfan (6.0 mg/ml) 6,000 ppm	>240
3) Carboplatin (10.0 mg/ml) 10,000 ppm	>240
4) Carmustine (3.3 mg/ml) 3,300 ppm	73.7
5) Cisplatin (1.0 mg/ml) 1,000 ppm	>240
6) Cyclophosphamide (20.0 mg/ml) 20,000 ppm	>240
7) Cytarabine (100.0 mg/ml) 100,000 ppm	>240
8) Dacarbazine (10.0 mg/ml) 10,000 ppm	>240
9) Daunorubicin HCl (5.0 mg/ml) 5,000 ppm	>240
10) Docetaxel (10.0 mg/ml) 10,000 ppm	>240
11) Doxorubicin HCl (2.0 mg/ml) 2,000 ppm	>240
12) Epirubicin HCl (2.0 mg/ml) 2,000 ppm	>240
13) Etoposide (20.0 mg/ml) 20,000 ppm	>240
14) Fludarabine (25.0 mg/ml) 25,000 ppm	>240

15) Fluorouracil (50.0 mg/ml 50,000 ppm	>240
16) Gemcitabine (38.0 mg/ml) 38,000 ppm	>240
17) Idarubicin HCl (1.0 mg/ml) 1,000 ppm	>240
18) Ifosfamide (50.0 mg/ml) 50,000 ppm	>240

19) Irinotecan (20.0 mg/ml) 20,000 ppm	>240
20) Mechlorethamine HCl (1.0 mg/ml) 1,000 ppm	>240
21) Melphalan (5.0 mg/ml) 5,000 ppm	>240
22) Methotrexate (25.0 mg/ml) 25,000 ppm	>240
23) Mitomycin C (0.5 mg/ml) 500 ppm	>240
24) Mitoxantrone (2.0 mg/ml) 2,000 ppm	>240
25) Paclitaxel (6.0 mg/ml) 6,000 ppm	>240
26) Rituximab (10.0 mg/ml) 10,000 ppm	>240
27) ThioTepa (10.0 mg/ml)10,000 ppm	25.4
28) Trisenox (1.0 mg/ml) 1,000 ppm	>240
29) Vincristine Sulfate (1.0 mg/ml) 1,000 ppm	>240

The maximum testing time is 240 minutes. Warning: Do not use with Carmustine or ThioTepa.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

<table>
<tr><th rowspan="2">Characteristics</th><th>Proposed Device</th><th>Predicate Device</th><th rowspan="2">Comparison</th></tr>
<tr><th>SHOWA® Blue Nitrile Powder Free Medical Examination Glove K211003</th><th>Polymer Patient Examination Glove 510(k) Number K200581</th></tr>
<tr><td>Device Description/ Regulation Number</td><td>Patient examination glove 21 CFR § 880.6250</td><td>Patient examination glove 21 CFR § 880.6250</td><td>Same</td></tr>
<tr><td>Product Code</td><td>LZA, LZC</td><td>LZA, LZC, QDO</td><td>Similar</td></tr>
<tr><td>Indications for Use</td><td>A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner’s hands or fingers to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by chemotherapy drugs.

<table>
<tr><th>Chemotherapy Drugs and Concentration</th><th>Minimum Breakthrough, detection time in minutes, minutes</th></tr>
<tr><td>1) Blenoxane (15.0 mg/ml) 15,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>2) Busulfan (6.0 mg/ml) 6,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>3) Carboplatin (10.0 mg/ml) 10,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>4) Carmustine (3.3 mg/ml) 3,300 ppm</td><td>73.7 minutes</td></tr>
</table>
</td><td>Biodegradable Nitrite Powder Free Examination Gloves 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 D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
<table>
<tr><th>Chemotherapy Drug and Concentration</th><th>Minimum Breakthrough Detection Time in Minutes</th></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>21.4</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Cyclophosphamide (20.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Dacarbazine (10.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Doxorubicin Hydrochloride (2.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Etoposide (20.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Fluorouracil (50.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Methotrexate (25.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Mitomycin C (0.5 mg/ml)</td><td>>240</td></tr>
</table>
</td><td>Similar</td></tr>
</table>

5) Cisplatin (1.0 mg/ml) 1,000 ppm	>240 minutes
6) Cyclophosphamide (20.0 mg/mll) 20,000 ppm	>240 minutes
7) Cytarabine (100.0 mg/ml)	>240 minutes

Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	67.2
Vincristine Sulfate (1.0 mg/ml)	>240
Azacytidine (25.0 mg/ml)	>240

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<table>
<tr><td>100,000 ppm</td><td></td></tr>
<tr><td>8) Dacarbazine (10.0 mg/ml) 10,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>9) Daunorubicin HCl (5.0 mg/ml) 5,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>10) Docetaxel (10.0 mg/ml) 10,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>11) Doxorubicin HCl (2.0 mg/ml) 2,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>12) Epirubicin HCl (2.0 mg/ml) 2,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>13) Etoposide (20.0 mg/ml) 20,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>14) Fludarabine (25.0 mg/ml) 25,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>15) Fluorouracil (50.0 mg/ml 50,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>16) Gemcitabine (38.0 mg/ml) 38,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>17) Idarubicin HCl (1.0 mg/ml) 1,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>18) Ifosfamide (50.0 mg/ml) 50,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>19) Irinotecan (20.0 mg/ml) 20,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>20) Mechlorethamine HCl (1.0 mg/ml) 1,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>21) Melphalan (5.0 mg/ml) 5,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>22) Methotrexate (25.0 mg/ml) 25,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>23) Mitomycin C (0.5 mg/ml) 500 ppm</td><td>>240 minutes</td></tr>
<tr><td>24) Mitoxantrone (2.0 mg/ml) 2,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>25) Paclitaxel (6.0 mg/ml) 6,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>26) Rituximab (10.0 mg/ml) 10,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>27) ThioTepa (10.0 mg/ml)10,000 ppm</td><td>25.4 minutes</td></tr>
<tr><td>28) Trisenox (1.0 mg/ml) 1,000 ppm</td><td>>240 minutes</td></tr>
<tr><td>29) Vincristine Sulfate (1.0 mg/ml) 1,000 ppm</td><td>>240 minutes</td></tr>
</table>
The maximum testing time is 240 minutes.
Warning: Do not use with Carmustine or ThioTepa.
</td>
<td>
<table>
<tr><td>Carboplatin (10.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Docetaxel (10 mg/ml)</td><td>>240</td></tr>
<tr><td>Epirubicin (2.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Gemcitabine (38 nig/ml)</td><td>>240</td></tr>
<tr><td>Ifosfamide {50 mg/ml)</td><td>>240</td></tr>
<tr><td>Irinotecan (20 mg/ml)</td><td>>240</td></tr>
<tr><td>Mitoxantrone (2.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Oncovin (l.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Oxaliplatin (5 mg/ml)</td><td>>240</td></tr>
<tr><td>Vinorelbine (] 0 mg/ml)</td><td>>240</td></tr>
</table>
Please note that Carmustine and Thiotepa have extremely low penetration times of 21.4 minutes and 67.2 minutes respectively.
Warning: Do not use with Carmustine
<table>
<tr><td>Fentanyl Citrate and Concentration</td><td>Minimum Breakthrough Detection Time in Minutes</td></tr>
<tr><td>Fentanyl Citrate Injection (100 mcg/2ml)</td><td>>240</td></tr>
</table>
</td>
<td></td>
</tr>
<tr><td>Material Use</td><td>Nitrile</td><td>Nitrile</td><td>Same</td></tr>
<tr><td>Color</td><td>Blue</td><td>Blue</td><td>Same</td></tr>
<tr><td>Sterility</td><td>Non-Sterile</td><td>Non-Sterile</td><td>Same</td></tr>
<tr><td>Dimensions</td><td>Meets ASTM D6319-10</td><td>Meets ASTM D6319-10</td><td>Same</td></tr>
<tr><td>Physical Properties</td><td>Meets ASTM D6319-10</td><td>Meets ASTM D6319-10</td><td>Same</td></tr>
<tr><td>Freedom from Holes (D 5151)</td><td>AQL 2.5 Inspection Meets ASTM D5151-06</td><td>AQL 2.5 Inspection Meets ASTM D5151-06</td><td>Same</td></tr>
<tr><td>Residual Powder (D 6124)</td><td>Meets ASTM D6124-06</td><td>Meets ASTM D6124-06</td><td>Same</td></tr>
<tr><td>Biocompatibility test – Primary Skin Irritation Test (ISO 10993-10)</td><td>Under the conditions of the study, not a primary skin irritant.</td><td>Under the conditions of the study, not a primary skin irritant.</td><td>Same</td></tr>
</table>

Biocompatibility test – Dermal Sensitization Assay (ISO 10993-10)	Under conditions of the study, not a contact sensitizer	Under conditions of the study, not a contact sensitizer	Same
Biocompatibility test – Acute	Under conditions of the ISO Acute Systemic Injection test, not toxic	Under conditions of the ISO Acute Systemic Injection test, not toxic	Same

systemic toxicity Study (ISO 10993-11)			
Resistance against Chemotherapy Drugs Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASTM D6978-5 (2013)	Breakthrough greater than 240 min. • Blenoxane (15.0 mg/ml) • Busulfan (6.0 mg/ml) • Carboplatin (10.0 mg/ml) • Cisplatin (1.0 mg/ml) • Cyclophosphamide (20.0 mg/ml) • Cytarabine (100.0 mg/ml) • Dacarbazine (10.0 mg/ml) • Daunorubicin HCl (5.0 mg/ml) • Docetaxel (10.0 mg/ml) • Doxorubicin HCl (2.0 mg/ml) • Epirubicin HCl (2.0 mg/ml) • Etoposide (20.0 mg/ml) • Fludarabine (25.0 mg/ml) • Fluorouracil (50.0 mg/ml • Gemcitabine (38.0 mg/ml) • Idarubicin HCl (1.0 mg/ml) • Ifosfamide (50.0 mg/ml) • Irinotecan (20.0 mg/ml) • Mechlorethamine HCl (1.0 mg/ml) • Melphalan (5.0 mg/ml) • Methotrexate (25.0 mg/ml) • Mitomycin C (0.5 mg/ml) • Mitoxantrone (2.0 mg/ml) • Paclitaxel (6.0 mg/ml) • Rituximab (10.0 mg/ml) • Trisenox (1.0 mg/ml) • Vincristine Sulfate (1.0 mg/ml) Breakthrough at 73.7 min. Carmustine (3.3 mg/ml) Breakthrough at 25.4 min. ThioTepa (10.0 mg/ml)	Breakthrough greater than 240 min. • 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) • Vincristine Sulfate (1.0 mg/ml) • Azacytidine (25.0 mg/m1) • Carboplatin (10.0 mg/ml) • Docetaxel (10 mg/ml) • Epirubicin (2.0 mg/ml) • Gemcitabine (38 mg/ml) • Ifosfamide {50 mg/ml) • Irinotecan (20 mg/ml) • Mitoxantrone (2.0 mg/ml) • Oncovin (l.0 mg/ml) • Oxaliplatin (5 mg/ml) • Vinorelbine (10 mg/ml) • Fentanyl Citrate (100 mcg/2ml) Breakthrough at 21.4 min. Carmustine (3.3 mg/ml) Breakthrough at 67.2 min. Thiotepa (10.0 mg/ml)	Similar

IX. SUMMARY OF NONCLINICAL TESTING

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319-10	Demonstrate accurate sizing	Dimensions Overall Length (mm) = 220 mm (sizes XS – S) and 230 mm (sixes M – XL) Width (± 10 mm) Size XS = 70 mm Size S = 80 mm Size M = 95 mm Size L = 110 mm Size XL = 120 mm Thickness at Palm (mm) = 0.05 min. Thickness at Finger Tip (mm) = 0.05 min.	Pass

ASTM D6319-10	Demonstrate tensile conforming properties	Before Aging (D 412): Tensile Strength (MPa) = 14 min Ultimate Elongation (%) = 500 min. After Aging (D 573) (70^{O}C ± 2°C for 166 hrs ± 2 hrs.): Tensile Strength (MPa) = 14 min Ultimate Elongation (%) = 400 min	Pass

ASTM D6319-10	Demonstrate glove integrity	Freedom from Holes (D 5151) AQL 2.5 Inspection Level G-1	Pass
ASTM D6319-10	Demonstrate biocompatibility: Residual powder	Residual Powder (D 6124) ≤ 2.0 mg/pc	Pass
Primary Skin Irritation Test ISO 10993-10	Demonstrate biocompatibility: Skin irritation	Under the conditions of the study, Not a primary skin irritant.	Pass
Dermal Sensitization Assay ISO 10993-10	Demonstrate biocompatibility: Skin sensitivity	Under the conditions of the study, Not a contact sensitizer.	Pass
Acute Systemic toxicity Study ISO 10993-11	Demonstrate biocompatibility: acute systemic toxicity	Under conditions of the ISO Acute Systemic Injection test, not toxic	Pass
Open box testing AAMI 11737-1	Demonstrate acceptable open box bioburden	Acceptable bioburden levels after 30 days open box	Pass

X. SUMMARY OF CLINICAL TESTING

No clinical testing was performed.

XI. CONCLUSION

The conclusions drawn from the non-clinical testing demonstrates that the SHOWA® Blue Nitrile Powder Free Medical Examination Glove is as safe, as effective, and performs as well or better than the legally marketed device (K200581).