February 26, 2024

Eco Medi Glove Sdn. Bhd.
Suresh Kumar Sivalingam
QA Manager
Lot 23826, Jalan Tembaga Kuning
Kamunting Raya Industrial Estate
Taiping, Perak Darul Ridzuan 34600
Malaysia

Re: K233560
Trade/Device Name: Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid
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 28, 2023
Received: November 28, 2023

Dear Suresh Kumar Sivalingam:

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.

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

DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233560

Device Name
Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid

Indications for Use *(Describe)*
Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid is a disposable device intended for medical purposes that are worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is for over-the-counter use.

In addition, these gloves were tested for use with Chemotherapy drugs, Fentanyl, and Gastric Acid in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

Chemotherapy Drug and Fentanyl Concentration	Minimum Breakthrough detection time in Minutes
1. Bendamustine HCl 5mg/ml (5,000ppm)	>240 minutes
2. Bleomycin Sulfate 15mg/ml (15,000ppm)	>240 minutes
3. Busulfan 6mg/ml (6,000 ppm)	>240 minutes
4. Carboplatin 10mg/ml (10,000 ppm)	>240 minutes
5. Carfilzomib 2mg/ml (2,000ppm)	>240 minutes
6. Carmustine 3.3mg/ml (3,300 ppm)	22.0 minutes
7. Cetuximab 2mg/ml (2,000 ppm)	>240 minutes
8. Cisplatin 1mg/ml (1,000ppm)	>240 minutes
9. Cladribine 1mg/ml (1,000ppm)	>240 minutes
10. Cyclophosphamide, 20 mg/ml (20,000ppm)	>240 minutes
11. Cytarabine (Cytosine), (100,000ppm)	>240 minutes
12. Dacarbazine, 10mg/ml (10,000ppm)	>240 minutes
13. Daunorubicin, HCI, 5mg/ml (5,000 ppm)	>240 minutes
14. Decitabine, 5mg/ml (5,000 ppm)	>240 minutes
15. Docetaxel 10mg/ml (10,000ppm)	>240 minutes
16. Doxorubicin HCI, 2mg/ml (2,000 ppm)	>240 minutes
17. Epirubicin HCl, 2mg/ml (2,000 ppm)	>240 minutes
18. Etoposide, 20mg/ml (20,000 ppm)	>240 minutes
19. Fludarabine Phosphate, 25mg/ml (25,000 ppm)	>240 minutes
20. Fluorouracil, 50 mg/ml (50,000 ppm)	>240 minutes
21. Gemcitabine, HCI, 38mg/ml (38,000 ppm)	>240 minutes
22. Idarubicin HCI, 1mg/ml (1,000ppm)	>240 minutes
23. Ifosfamide, 50mg/ml (50,000 ppm)	>240 minutes
24. Irinotecan, HCI, 20mg/ml (20,000ppm)	>240 minutes
25. Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	>240 minutes
26. Melphalan HCI, 5mg/ml (5,000 ppm)	>240 minutes
27. Methotrexate, 25mg/ml (25,000 ppm)	>240 minutes
28. Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
29. Mitoxantrone HCI, 2mg/ml (2,000 ppm)	>240 minutes
30. Oxaliplatin, 5mg/ml (5,000ppm)	>240 minutes
31. Paclitaxel, 6mg/ml (6,000ppm)	>240 minutes
32. Paraplatin, 10mg/ml (10,000 ppm)	>240 minutes
33. Pemetrexed, 25mg/ml (25,000 ppm)	>240 minutes

34. Raltitrexed, 0.5mg/ml (500 ppm)	>240 minutes
35. Thiotepa, 10mg/ml (10,000 ppm)	34.2 minutes
36. Topotecan, 1mg/ml (1,000 ppm)	>240 minutes
37. Trisenox (Arsenic Trioxide), 1mg/ml (1,000ppm)	>240 minutes
38. Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240 minutes
39. Vidaza (Azacytidine) 25mg/ml (25,000 ppm)	>240 minutes
40. Vinblastine Sulfate, 1mg/ml (1,000 ppm)	>240 minutes
41. Vincristine Sulfate 1mg/ml (1,000 ppm)	>240 minutes
42. Zoledronic Acid, 0.8mg/ml (800 ppm)	>240 minutes

Other Drugs, Fentanyl and Gastric Acid Concentration	Minimum Breakthrough detection time in Minutes
1. Cytovene (Ganciclovir), (10,000ppm)	>240 minutes
2. Retrovir 10mg/ml (10,000 ppm)	>240 minutes
3. Triclosan, 3mg/ml (3,000 ppm)	>240 minutes
4. Fentanyl Citrate Injection 100mcg/2ml	>240 minutes
5. Simulated Gastric Acid	>240 minutes

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
Carmustine (BCNU) (3.3mg/ml)- Minimum Breakthrough detection time 22.0 minutes.
Thiotepa (10ug/ml) – Minimum Breakthrough detection time 34.2 minutes.

WARNING: Not for 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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SST NO. : A11-1808-21015730

510(K) Summary
K233560

Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid

1.0 Submitter:

Company Name	:	ECO Medi Glove Sdn. Bhd.
Company Address	:	Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping, Perak Darul Ridzuan, Malaysia.
Contact Person	:	Mr. Suresh Kumar Sivalingam
Telephone	:	+605-806 2316
Fax	:	+605-806 2315
Email	:	qa1@riverstone.com.my

2.0 Preparation Date : 26th February 2024

3.0 Name of the Device

Trade Name / Proprietary Name: Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid

Device Name: Low Dermatitis Nitrile Patient Examination gloves.

Device Classification Name: Non-Powdered Patient Examination Glove

Device Regulation Number: 21 CFR 880.6250

Device Class: Class I.

Product Code: LZA, LZC, QDO and OPJ

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TEL +60-5-806 2316 FAX +60-5-895 7668
SST NO. : A11-1808-21015730

4.0 Identification of The Legally Marketed Device:

Predicate Device: K181066, Powder Free Examination Glove (Blue) with Low Dermatitis Claim and with tested for use with Chemotherapy Drugs Claims.

Predicate Device Manufacturer: ECO Medi Glove Sdn. Bhd.

Reference Predicate: K202622, Halyard Lavender, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Reference Device Manufacturer: O & M Halyard, Inc.

This reference predicate is being used to support additional chemotherapy and other drugs that were not tested in the predicate.

5.0 Device Description

The subject device in this 510(k) Notification is Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid. The subject device is a patient examination glove made from nitrile latex compound, Blue color, powder-free, and non-sterile (Per 21 CFR 880.6250, class I) and come in eight sizes (XXS, XS, S, M, L, XL, and XXL). The device meets all the specifications in ASTM D6319-19, the Standard Specification for Nitrile Examination Gloves and Modified Draize Test. Additionally, the gloves have been tested for biocompatibility and permeability to chemotherapy drugs, fentanyl, and Gastric Acid.

6.0 Indications for Use

Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid is a disposable device intended for medical purposes that are worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is for over-the-counter use.

In addition, these gloves were tested for use with Chemotherapy drugs, Fentanyl, and gastric acid in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

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SST NO. : A11-1808-21015730

No.	Chemotherapy Drug Concentration	Minimum Breakthrough detection time in Minutes
1	Bendamustine HCl 5mg/ml (5,000ppm)	>240 minutes
2	Bleomycin Sulfate 15mg/ml (15,000ppm)	>240 minutes
3	Busulfan 6mg/ml (6,000 ppm)	>240 minutes
4	Carboplatin 10mg/ml (10,000 ppm)	>240 minutes
5	Carfilzomib 2mg/ml (2,000ppm)	>240 minutes
6	Carmustine 3.3mg/ml (3,300 ppm)	22.0 minutes
7	Cetuximab 2mg/ml (2,000 ppm)	>240 minutes
8	Cisplatin 1mg/ml (1,000ppm)	>240 minutes
9	Cladribine 1mg/ml (1,000ppm)	>240 minutes
10	Cyclophosphamide, 20 mg/ml (20,000ppm)	>240 minutes
11	Cytarabine (Cytosine), (100,000ppm)	>240 minutes
12	Dacarbazine, 10mg/ml (10,000ppm)	>240 minutes
13	Daunorubicin, HCI, 5mg/ml (5,000 ppm)	>240 minutes
14	Decitabine, 5mg/ml (5,000 ppm)	>240 minutes
15	Docetaxel 10mg/ml (10,000ppm)	>240 minutes
16	Doxorubicin HCI, 2mg/ml (2,000 ppm)	>240 minutes
17	Epirubicin HCl, 2mg/ml (2,000 ppm)	>240 minutes
18	Etoposide, 20mg/ml (20,000 ppm)	>240 minutes
19	Fludarabine Phosphate, 25mg/ml (25,000 ppm)	>240 minutes
20	Fluorouracil, 50 mg/ml (50,000 ppm)	>240 minutes
21	Gemcitabine, HCI, 38mg/ml (38,000 ppm)	>240 minutes
22	Idarubicin HCI, 1mg/ml (1,000ppm)	>240 minutes
23	Ifosfamide, 50mg/ml (50,000 ppm)	>240 minutes
24	Irinotecan, HCI, 20mg/ml (20,000ppm)	>240 minutes
25	Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	>240 minutes
26	Melphalan HCI, 5mg/ml (5,000 ppm)	>240 minutes
27	Methotrexate, 25mg/ml (25,000 ppm)	>240 minutes
28	Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
29	Mitoxantrone HCI, 2mg/ml (2,000 ppm)	>240 minutes
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32	Paraplatin, 10mg/ml (10,000 ppm)	>240 minutes
33	Pemetrexed, 25mg/ml (25,000 ppm)	>240 minutes
34	Raltitrexed, 0.5mg/ml (500 ppm)	>240 minutes
35	Thiotepa, 10mg/ml (10,000 ppm)	34.2 minutes
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37	Trisenox (Arsenic Trioxide), 1mg/ml (1,000ppm)	>240 minutes

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SST NO. : A11-1808-21015730

No.	Chemotherapy Drug Concentration	Minimum Breakthrough detection time in Minutes
38	Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240 minutes
39	Vidaza (Azacytidine) 25mg/ml (25,000 ppm)	>240 minutes
40	Vinblastine Sulfate, 1mg/ml (1,000 ppm)	>240 minutes
41	Vincristine Sulfate 1mg/ml (1,000 ppm)	>240 minutes
42	Zoledronic Acid, 0.8mg/ml (800 ppm)	>240 minutes
No.	Other Drugs, Fentanyl and Gastric Acid Concentration	Minimum Breakthrough detection time in Minutes
1	Cytovene (Ganciclovir), 10,000ppm)	>240 minutes
2	Retrovir 10mg/ml (10,000 ppm)	>240 minutes
3	Triclosan, 3mg/ml (3,000 ppm)	>240 minutes
4	Fentanyl Citrate Injection 100mcg/2ml	>240 minutes
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The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
Carmustine (BCNU) (3.3mg/ml)- Minimum Breakthrough detection time 22.0 minutes.
Thiotepa (10ug/ml) – Minimum Breakthrough detection time 34.2 minutes.

WARNING: Not for use with Carmustine and ThioTepa

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7.0 Summary of the Technological Characteristics

Comparison of Proposed and Predicate Devices

Characteristics	Acceptance Criteria	Subject Device Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid	Predicate Device Powder Free Examination Gloves (Blue) with Low Dermatitis Claim and with Tested for use with Chemotherapy Drugs Claims K181066	Comparison Analysis
Product Code	LZA, LZC, QDO and OPJ	LZA, LZC, QDO and OPJ	LZA, LZC	The subject device and predicate device have differences with the addition of QDO & OPJ for the subject device.
Regulation Number	880.6250	880.6250	880.6250	Same
Device Classification	Class 1	Class 1	Class 1	Same
Intended use	A powder-free 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. The device is for over-the-counter use.	A powder-free 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. The device is for over-the-counter use.	A powder-free 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. The device is for over-the-counter use.	Same
Material use	Nitrile compound	Nitrile compound	Nitrile compound	Same
Color	Blue	Blue	Blue	Same
Sterility	Non sterile	Non sterile	Non sterile	Same
Single use	Single use	Single use	Single use	Same
Surface	Finger Textured	Finger Textured	Finger Textured	Same
Cuffing Beading	Rolled Beading	Rolled Beading	Rolled Beading	Same
Design	Ambidextrous	Ambidextrous	Ambidextrous	Same

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<table>
<tr><th>Characteristics</th><th>Acceptance Criteria</th><th>Subject Device
Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid</th><th>Predicate Device
Powder Free Examination Gloves (Blue) with Low Dermatitis Claim and with Tested for use with Chemotherapy Drugs Claims
K181066</th><th>Comparison Analysis</th></tr>
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<td>Dimensions

Reference Standard ASTN D6319-19</td>
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<tr><td>XXS</td><td>Not indicated</td><td>Not indicated</td></tr>
<tr><td>XS</td><td>220mm</td><td>70mm</td></tr>
<tr><td>S</td><td>220mm</td><td>80mm</td></tr>
<tr><td>M</td><td>230mm</td><td>95mm</td></tr>
<tr><td>L</td><td>230mm</td><td>110mm</td></tr>
<tr><td>XL</td><td>230mm</td><td>120mm</td></tr>
<tr><td>XXL</td><td>230mm</td><td>130mm</td></tr>
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Thickness
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<tr><td>Palm</td><td>Min 0.05mm</td></tr>
<tr><td>Finger Tip</td><td>Min 0.05mm</td></tr>
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<tr><td>S</td><td>220mm</td><td>85mm</td></tr>
<tr><td>M</td><td>230mm</td><td>95mm</td></tr>
<tr><td>L</td><td>230mm</td><td>105mm</td></tr>
<tr><td>XL</td><td>230mm</td><td>115mm</td></tr>
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Thickness
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<tr><td>Palm</td><td>Min 0.05mm</td></tr>
<tr><td>Finger Tip</td><td>Min 0.05mm</td></tr>
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<td>Different:

Additional sizes XXS, XS, and XXL were added to the subject device.

The XXS and XS are applicable for smaller hand sizes users.

The XXL is applicable for larger hand sizes users.</td>
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<table>
<tr><th></th><th>Before Ageing</th><th>After Aging at 70ºC for 168 hrs @ 100ºC for 22 hrs</th></tr>
<tr><td>Tensile Strength (MPa)</td><td>14min</td><td>14min</td></tr>
<tr><td>Ultimate Elongation</td><td>500min</td><td>400min</td></tr>
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<td>Same</td>
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ECO Medi Glove Sdn. Bhd. (815262-D)
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TEL +60-5-806 2316 FAX +60-5-895 7668
SST NO. : A11-1808-21015730

Characteristics	Acceptance Criteria	Subject Device Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid	Predicate Device Powder Free Examination Gloves (Blue) with Low Dermatitis Claim and with Tested for use with Chemotherapy Drugs Claims K181066	Comparison Analysis
Freedom from Pinholes ASTM D5151-19	AQL 2.5 Inspection Level G-1	Passes AQL 1.5 Inspection Level: G1	Passes AQL 1.5 Inspection Level: G1	Same
Residual Powder ASTM D6124-06	≤ 2.0 mg/glove	≤2 mg/glove	≤2 mg/glove	Same
Dermal Irritation ISO 10993-23:2021	Under the conditions of the study, the device is not an irritant.	Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.	Same
Dermal Sensitization ISO 10993-10: 2021	Under the conditions of the study, the device is not a sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	Same
Acute Systemic Toxicity ISO 10993-11	Under the conditions of this study, the test article does not induce systemic toxicity.	Under the conditions of this study, the test article did not induce any systemic toxicity.	Under the conditions of this study, the test article did not induce any systemic toxicity.	Same
Low Dermatitis Potential claim Modified Draize 95 Test	No clinical evidence presence of residual chemical additives that may induce type IV allergy in human subject.	There was no clinical evidence of the presence of residual chemical additives at the level that may induce type IV allergy in the un-sensitized general user population in the test articles.	There was no clinical evidence of the presence of residual chemical additives at the level that may induce type IV allergy in the un-sensitized general user population in the test articles.	Same

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Characteristics		Acceptance Criteria	Subject Device Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid	Reference Predicate Halyard Lavender, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate K202622	Predicate Device Powder Free Examination Gloves (Blue) with Low Dermatitis Claim and with Tested for use with Chemotherapy Drugs Claims K181066	Comparison Analysis
Chemotherapy Drug Permeation Test			**Minimum Breakthrough detection time in Minutes**			———
No.	**Chemotherapy Drug/Concentration**					
1	Bendamustine HCl 5mg/ml (5,000ppm)	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASM D6978-05	>240 minutes	>240 minutes	/	Same
2	Bleomycin Sulfate 15mg/ml (15,000ppm)		>240 minutes	>240 minutes	/	Same
3	Busulfan 6mg/ml (6,000 ppm)		>240 minutes	>240 minutes	/	Same
4	Carboplatin 10mg/ml (10,000 ppm)		>240 minutes	>240 minutes	/	Same
5	Carfilzomib 2mg/ml (2,000ppm)		>240 minutes	>240 minutes	/	Same
6	Carmustine 3.3mg/ml (3,300 ppm)		22.0 minutes	0.3 minutes	12.9 minutes	Similar
7	Cetuximab 2mg/ml (2,000 ppm)		>240 minutes	>240 minutes	/	Same
8	Cisplatin 1mg/ml (1,000ppm)		>240 minutes	>240 minutes	>240 minutes	Same
9	Cladribine 1mg/ml (1,000ppm)		>240 minutes	>240 minutes	/	Same
10	Cyclophosphamide 20 mg/ml (20,000ppm)		>240 minutes	>240 minutes	>240 minutes	Same
11	Cytarabine (Cytosine) (100,000ppm)		>240 minutes	>240 minutes	/	Same
12	Dacarbazine 10mg/ml (10,000ppm)		>240 minutes	>240 minutes	/	Same
13	Daunorubicin HCl 5mg/ml (5,000 ppm)		>240 minutes	>240 minutes	/	Same
14	Decitabine 5mg/ml (5,000 ppm)		>240 minutes	>240 minutes	/	Same
15	Docetaxel 10mg/ml (10,000ppm)		>240 minutes	>240 minutes	/	Same
16	Doxorubicin HCl 2mg/ml (2,000 ppm)		>240 minutes	>240 minutes	>240 minutes	Same
17	Epirubicin HCl 2mg/ml (2,000 ppm)		>240 minutes	>240 minutes	/	Same
18	Etoposide 20mg/ml (20,000 ppm)		>240 minutes	>240 minutes	>240 minutes	Same
19	Fludarabine Phosphate 25mg/ml (25,000 ppm)		>240 minutes	>240 minutes	/	Same
20	Fluorouracil 50 mg/ml (50,000 ppm)		>240 minutes	>240 minutes	>240 minutes	Same
21	Gemcitabine, HCl 38mg/ml (38,000 ppm)		>240 minutes	>240 minutes	/	Same
22	Idarubicin HCl 1mg/ml (1,000ppm)		>240 minutes	>240 minutes	/	Same

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Chemotherapy Drug Permeation Test			**Minimum Breakthrough detection time in Minutes**			
No.	**Chemotherapy Drug/Concentration**					
23	Ifosfamide 50mg/ml (50,000 ppm)	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASM D6978-05	>240 minutes	>240 minutes	/	Same
24	Irinotecan HCI, 20mg/ml (20,000ppm)		>240 minutes	>240 minutes	/	Same
25	Mechlorethamine HCl 1 mg/ml (1,000 ppm)		>240 minutes	>240 minutes	/	Same
26	Melphalan HCI 5mg/ml (5,000 ppm)		>240 minutes	>240 minutes	/	Same
27	Methotrexate 25mg/ml (25,000 ppm)		>240 minutes	>240 minutes	>240 minutes	Same
28	Mitomycin C 0.5mg/ml (500 ppm)		>240 minutes	>240 minutes	/	Same
29	Mitoxantrone HCI 2mg/ml (2,000 ppm)		>240 minutes	>240 minutes	/	Same
30	Oxaliplatin 5mg/ml (5,000ppm)		>240 minutes	>240 minutes	/	Same
31	Paclitaxel 6mg/ml (6,000ppm)		>240 minutes	>240 minutes	>240 minutes	Same
32	Paraplatin 10mg/ml (10,000 ppm)		>240 minutes	/	/	Same
33	Pemetrexed 25mg/ml (25,000 ppm)		>240 minutes	>240 minutes	/	Same
34	Raltitrexed 0.5mg/ml (500 ppm)		>240 minutes	>240 minutes	/	Same
35	Thiotepa 10mg/ml (10,000 ppm)		34.2 minutes	30.9 minutes	27.7 minutes	Similar
36	Topotecan 1mg/ml (1,000 ppm)		>240 minutes	>240 minutes	/	Same
37	Trisenox (Arsenic Trioxide) 1mg/ml (1,000ppm)		>240 minutes	>240 minutes	/	Same
38	Velcade (Bortezomib) 1mg/ml (1,000ppm)		>240 minutes	/	/	*Different
39	Vidaza (Azacytidine) 25mg/ml (25,000 ppm)		>240 minutes	/	/	*Different
40	Vinblastine Sulfate 1mg/ml (1,000 ppm)		>240 minutes	>240 minutes	/	Same
41	Vincristine Sulfate 1mg/ml (1,000 ppm)		>240 minutes	>240 minutes	/	Same
42	Zoledronic Acid 0.8mg/ml (800 ppm)		>240 minutes	>240 minutes	/	Same

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Characteristics		Acceptance Criteria	Subject Device Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid	Reference Predicate Halyard Lavender, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate K202622	Predicate Device Powder Free Examination Gloves (Blue) with Low Dermatitis Claim and with Tested for use with Chemotherapy Drugs Claims K181066	Comparison Analysis
Drug/Chemical Permeation Test		Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASM D6978-05	**Minimum Breakthrough detection time in Minutes**			
No.	**Drug, Chemical /Concentration**					
1	Cytovene (Ganciclovir) 10,000ppm)		>240 minutes	>240 minutes	/	Same
2	Retrovir 10mg/ml (10,000 ppm)		>240 minutes	>240 minutes	/	Same
3	Triclosan 3mg/ml (3,000 ppm)		>240 minutes	>240 minutes	/	Same
4	Fentanyl Citrate Injection 100mcg/2ml		>240 minutes	>240 minutes	/	Same
5	Simulated Gastric Acid		>240 minutes	/	/	*Different

*Subject glove has been tested with additional chemotherapy drugs and simulated gastric acid to meet current user demand and to meet competitive market demand.

Carmustine (BCNU) (3.3mg/ml)- Minimum Breakthrough detection time 22.0 minutes. Thiotepa (10ug/ml) – Minimum Breakthrough detection time 34.2 minutes.

WARNING: Not for use with Carmustine and ThioTepa

8.0 Summary of Non-Clinical Performance Test Data

Test Methodology	Test Standard	Acceptance Criteria	Test Result
Freedom from Pin Holes	ASTM D5151 -19 (Re-approved 2011) Standard Test Method for Detection of Holes in Medical Gloves	AQL 2.5 Inspection Level G-1	Pass
Physical Dimensions	ASTM D6319 -19 Standard Specification for Nitrile Examination Gloves for Medical Application	ISO 2859-1/ S2/AQL 4.0 Size / Length (min) / Width (± 10mm) XXS: Not indicated / Not indicated XS: 220mm / 70mm S: 220mm / 80mm M: 230mm / 95mm L: 230mm / 110mm XL: 230mm / 120mm XXL: 230mm / 130mm Thickness Palm: Min 0.05mm Finger Tip: Min 0.05mm	Pass

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Test Methodology	Test Standard	Acceptance Criteria	Test Result
Physical Properties	ASTM D6319 -19 Standard Specification for Nitrile Examination Gloves for Medical Application ASTM D412-16(2021) Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension	**Before Ageing** Tensile Strength (MPa)= 14min Ultimate Elongation (%)= 500min **After Aging at 70°C for 168 hrs @ 100°C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%)= 400min	Pass
Powder-free Residue	ASTM D6124-06 (2022) Standard Test Method for Residual Powder on Medical Gloves	≤ 2.0 mg/gloves	Pass
Acute Systemic Toxicity	ISO 10993-11 Biological evaluation on medical device Part 11 – Test for systemic toxicity	Under the conditions of this study, the test article does not induce acute systemic toxicity	Under the conditions of this study, the test article did not induce acute systemic toxicity
Dermal Sensitization	ISO 10993-10: 2021 Biological Evaluation on Medical Device – Part 10: Test for Skin Sensitization	Under the conditions of the study, the device is not a sensitizer	Under the conditions of this study, the test article was a non-sensitizer.
Primary Skin Irritation	ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Test for irritation	Under the conditions of the study, the device is not an irritant	Under the conditions of this study, the test article was a non-irritant.
Resistance against Chemotherapy Drugs, Fentanyl, and Gastric Acid	ASTM D6978-05 Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs	See Section 7.0	See Section 7.0

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9.0 Clinical Summary

Testing was performed in accordance with Modified Draize-95 Test, per FDA's guidance document "Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510k] Submissions for Testing Skin Sensitization Chemicals in Natural Rubber Products" (1999).

The age of the subjects ranged from 18 to 65 years who reasonably reflect the general user population in the US, gave all negative results. A total of 211 subjects, one hundred and fifty-one subjects were Caucasian (71.6%), thirty subjects were Afro Caribbean (14.0%) and 30 subjects were Asiatic (14.2%) were recruited into the study but six subjects was discontinued due to poor compliance. Hence 205 subjects completed the two stages of the study. Age range of the study subjects were between 18 – 60 years (mean 29.37 ± 11.37 years). One hundred and ninety subjects were female (58.0%) and eighty-six subjects were male (42.0%).

There was no clinical evidence of the presence of residual chemical additives at the level that may induce type IV allergy in the un-sensitized general user population in the test articles.

10.0 Conclusion

The Conclusions drawn from the non-clinical tests demonstrate that the subject device, Powder Free Nitrile Examination Glove Blue with Low Dermatitis Potential Claim, Tested for use with Chemotherapy Drugs, Fentanyl and Gastric Acid is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K181066.