July 21, 2026

O&M Halyard, Inc.
Sahrudin Shah
Regulatory Affairs Specialist
1220 Old Alpharetta Rd.
Suite 320
Alpharetta, Georgia 30005

Re: K262014
Trade/Device Name: PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves; PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: June 15, 2026
Received: June 15, 2026

Dear Sahrudin Shah:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K262014

Device Name
PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves
PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves

Indications for Use *(Describe)*
PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves - Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid Fluid.

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate, and a 50/50 mixture of Fentanyl Citrate and Simulated Gastric Fluid using ASTM D6978-05.

The following chemicals (chemotherapy and non-chemotherapy drugs) have been tested with these gloves:

Chemotherapy Drugs	Concentration mg/mL	Breakthrough Detection Time in Minutes
1 Cisplatin,	1mg/mL (1,000 ppm)	>240min
2 Cyclophosphamide (Cytoxan)	20mg/mL (20,000 ppm)	>240min
3 Dacarbazine (DTIC)	10mg/mL (10,000 ppm)	>240min
4 Doxorubicin HCI (Adriamycin)	2mg/mL (2,000 ppm)	>240min
5 Etoposide (Toposar)	20mg/mL (20,000 ppm)	>240min
6 Fluorouracil (5 Flu)	50mg/mL (50,000 ppm)	>240min
7 Ifosfamide (IFEX)	50mg/mL (50,000 ppm)	>240min
8 Methotrexate	25mg/mL (25,000 ppm)	>240min
9 Mitomycin C	0.5 mg/mL (500 ppm)	>240min
10 Mitoxantrone HCI	2mg/mL (2,000 ppm)	>240min
11 Paclitaxel (Taxol)	6mg/mL (6,000 ppm)	>240min
12 Vincristine Sulphate	1mg/mL (1,000 ppm)	>240 min
13 Carmustine	3.3mg/mL (3,300 ppm)	40 min
14 Thiotepa	10mg/mL (10,000 ppm)	88.6 min

Non-chemotherapy Drugs	Concentration mg/mL	Breakthrough Detection Time in Minutes
1 Fentanyl Citrate Injection	100mcg/2mL	>240min
2 Simulated Gastric Acid Fluid / Fentanyl Citrate Injection Mix 50/50 Solution	50% (v/v) mixture	>240min

The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:
Carmustine 3.3mg/mL (3,300 ppm), breakthrough detected at 40 minutes
Thiotepa 10mg/mL (10,000 ppm), breakthrough detected at 88.6 minutes

Warning: Not for use with Carmustine and Thiotepa

PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate, and a 50/50 mixture of Fentanyl Citrate and Simulated Gastric Fluid using ASTM D6978-05.

The following chemicals (chemotherapy and non-chemotherapy drugs) have been tested with these gloves:

Chemotherapy Drugs	Concentration mg/mL	Breakthrough Detection Time in Minutes
1 Cisplatin,	1mg/mL (1,000 ppm)	>240min
2 Cyclophosphamide (Cytoxan)	20mg/mL (20,000 ppm)	>240min
3 Dacarbazine (DTIC)	10mg/mL (10,000 ppm)	>240min
4 Doxorubicin HCI (Adriamycin)	2mg/mL (2,000 ppm)	>240min
5 Etoposide (Toposar)	20mg/mL (20,000 ppm)	>240min
6 Fluorouracil (5 Flu)	50mg/mL (50,000 ppm)	>240min
7 Ifosfamide (IFEX)	50mg/mL (50,000 ppm)	>240min
8 Methotrexate	25mg/mL (25,000 ppm)	>240min
9 Mitomycin C	0.5 mg/mL (500 ppm)	>240min
10 Mitoxantrone HCI	2mg/mL (2,000 ppm)	>240min
11 Paclitaxel (Taxol)	6mg/mL (6,000 ppm)	>240min
12 Vincristine Sulphate	1mg/mL (1,000 ppm)	>240 min
13 Carmustine	3.3mg/mL (3,300 ppm)	40 min
14 Thiotepa	10mg/mL (10,000 ppm)	88.6 min

Non-chemotherapy Drugs	Concentration mg/mL	Breakthrough Detection Time in Minutes
1 Fentanyl Citrate Injection	100mcg/2mL	>240min
2 Simulated Gastric Acid Fluid / Fentanyl Citrate Injection Mix 50/50 Solution	50% (v/v) mixture	>240min

The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:
Carmustine 3.3mg/mL (3,300 ppm), breakthrough detected at 40 minutes
Thiotepa 10mg/mL (10,000 ppm), breakthrough detected at 88.6 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.

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."

The assigned 510(k) Number: **K262014**

510(k) Summary

1. Date of Submission: **15th June 2026**

2. Sponsor Identification:

   O&M Halyard, Inc.
   1220 Old Alpharetta Road,
   Ste. 320, Alpharetta GA 30005 United States

3. Designated Submission Correspondent: **Mr. Sahrudin Shah, Regulatory Affairs Specialist**

4. Identification of Proposed Device:

   PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves
   PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves

   Regulatory Information

   Classification Name: Non-Powdered Patient Examination Glove

   Classification: I

Product Code: LZA, LZC, QDO, OPJ

Regulation Number: 880.6250

Regulation Name: Non-powdered patient examination glove

Review Panel: General Hospital

5. Identification of Predicate Device(s)

510(k) Number: **K220547**

6. Device Description:

PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves and **PURE**ZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves are disposable, blue-colored, ambidextrous, non-sterile nitrile examination gloves with beaded cuffs. These gloves have been tested for use with Chemotherapy drugs, Fentanyl Citrate, and a 50/50 mixture of Fentanyl Citrate and Simulated Gastric Fluid.

7. Indication For Use Statement:

PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate, and a 50/50 mixture of Fentanyl Citrate and Simulated Gastric Fluid using ASTM D6978-05. The following chemicals (chemotherapy and non-chemotherapy drugs) have been tested with these gloves:

No.	Chemotherapy Drugs	Breakthrough Detection Time in Minutes
1	Cisplatin, 1mg/mL (1,000 ppm)	> 240min
2	Cyclophosphamide (Cytoxan), 20mg/mL (20,000 ppm)	> 240min
3	Dacarbazine (DTIC), 10mg/mL (10,000 ppm)	> 240min
4	Doxorubicin HCI (Adriamycin), 2mg/mL (2,000 ppm)	> 240min
5	Etoposide (Toposar), 20mg/mL (20,000 ppm)	> 240min
6	Fluorouracil (5 Flu), 50mg/mL (50,000 ppm)	> 240min
7	Ifosfamide (IFEX), 50mg/mL (50,000 ppm)	> 240min
8	Methotrexate, 25mg/mL (25,000 ppm)	> 240min
9	Mitomycin C, 0.5 mg/mL (500 ppm)	> 240min
10	Mitoxantrone HCI, 2mg/mL (2,000 ppm)	> 240min
11	Paclitaxel (Taxol), 6mg/mL (6,000 ppm)	> 240min
12	Vincristine Sulphate, 1mg/mL (1,000 ppm)	> 240 min
13	Carmustine, 3.3mg/mL (3,300 ppm)	40 min
14	Thiotepa, 10mg/mL (10,000 ppm)	88.6 min
No.	Non-chemotherapy Drugs	Breakthrough Detection Time in Minutes
1	Fentanyl Citrate Injection, 100mcg/2mL	> 240min
2	Simulated Gastric Acid Fluid / Fentanyl Citrate Injection Mix 50/50 Solution	> 240min

The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:

Carmustine 3.3mg/mL (3,300 ppm), breakthrough detected at 40 minutes

Thiotepa 10mg/mL (10,000 ppm), breakthrough detected at 88.6 minutes

Warning: Not for use with Carmustine and Thiotepa

PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate, and a 50/50 mixture of Fentanyl Citrate and Simulated Gastric Fluid using ASTM D6978-05. The following chemicals (chemotherapy and non-chemotherapy drugs) have been tested with these gloves:

No.	Chemotherapy Drugs	Breakthrough Detection Time in Minutes
1	Cisplatin, 1mg/mL (1,000 ppm)	> 240min
2	Cyclophosphamide (Cytoxan), 20mg/mL (20,000 ppm)	> 240min
3	Dacarbazine (DTIC), 10mg/mL (10,000 ppm)	> 240min
4	Doxorubicin HCI (Adriamycin), 2mg/mL (2,000 ppm)	> 240min
5	Etoposide (Toposar), 20mg/mL (20,000 ppm)	> 240min
6	Fluorouracil (5 Flu), 50mg/mL (50,000 ppm)	> 240min
7	Ifosfamide (IFEX), 50mg/mL (50,000 ppm)	> 240min
8	Methotrexate, 25mg/mL (25,000 ppm)	> 240min
9	Mitomycin C, 0.5 mg/mL (500 ppm)	> 240min
10	Mitoxantrone HCI, 2mg/mL (2,000 ppm)	> 240min
11	Paclitaxel (Taxol), 6mg/mL (6,000 ppm)	> 240min
12	Vincristine Sulphate, 1mg/mL (1,000 ppm)	> 240 min
13	Carmustine, 3.3mg/mL (3,300 ppm)	40 min
14	Thiotepa, 10mg/mL (10,000 ppm)	88.6 min
No.	Non-chemotherapy Drugs	Breakthrough Detection Time in Minutes
1	Fentanyl Citrate Injection, 100mcg/2mL	> 240min
2	Simulated Gastric Acid Fluid / Fentanyl Citrate Injection Mix 50/50 Solution	> 240min

The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:

Carmustine 3.3mg/mL (3,300 ppm), breakthrough detected at 40 minutes

Thiotepa 10mg/mL (10,000 ppm), breakthrough detected at 88.6 minutes

Warning: Not for use with Carmustine and Thiotepa

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	**Proposed Device (K262014)**		**Predicate Device (K220547)**	Remark
Trade Name	PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves	PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves	PureZero MARIN Nitrile Powder-Free Exam Gloves, PureZero MARIN-XTRA Nitrile Powder-Free Exam Gloves	SAME
Product Code	LZA, LZC, QDO, OPJ		LZA, LZC, QDO, OPJ	SAME
Classification Regulation	21 CFR 880.6250		21 CFR 880.6250	SAME
Class	I		I	SAME
Indication for use	**PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves - Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid Fluid:** The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate, and a 50/50 mixture of Fentanyl Citrate and Simulated Gastric Fluid using ASTM D6978-05. The following chemicals (chemotherapy and non-chemotherapy drugs) have been tested with these gloves:	**PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves - Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid Fluid.** The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate, and a 50/50 mixture of Fentanyl Citrate and Simulated Gastric Fluid using ASTM D6978-05. The following chemicals (chemotherapy and non-chemotherapy drugs) have been tested with these gloves:	The PureZero MARIN Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim and PureZero MARIN-XTRA Nitrile Powder-Free Exam Gloves with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid claim is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Analysis 1

<table>
<tr>
<td></td>
<td>
<table>
<tr><th>No.</th><th>Chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr>
<tr><td>1</td><td>Cisplatin, 1mg/mL (1,000 ppm)</td><td>> 240min</td></tr>
<tr><td>2</td><td>Cyclophosphamide (Cytoxan), 20mg/mL (20,000 ppm)</td><td>> 240min</td></tr>
<tr><td>3</td><td>Dacarbazine (DTIC), 10mg/mL (10,000 ppm)</td><td>> 240min</td></tr>
<tr><td>4</td><td>Doxorubicin HCl (Adriamycin), 2mg/mL (2,000 ppm)</td><td>> 240min</td></tr>
<tr><td>5</td><td>Etoposide (Toposar), 20mg/mL (20,000 ppm)</td><td>> 240min</td></tr>
<tr><td>6</td><td>Fluorouracil (5 Flu), 50mg/mL (50,000 ppm)</td><td>> 240min</td></tr>
<tr><td>7</td><td>Ifosfamide (IFEX), 50mg/mL (50,000 ppm)</td><td>> 240min</td></tr>
<tr><td>8</td><td>Methotrexate, 25mg/mL (25,000 ppm)</td><td>> 240min</td></tr>
<tr><td>9</td><td>Mitomycin C, 0.5 mg/mL (500 ppm)</td><td>> 240min</td></tr>
<tr><td>10</td><td>Mitoxantrone HCl, 2mg/mL (2,000 ppm)</td><td>> 240min</td></tr>
<tr><td>11</td><td>Paclitaxel (Taxol), 6mg/mL (6,000 ppm)</td><td>> 240min</td></tr>
<tr><td>12</td><td>Vincristine Sulphate, 1mg/mL (1,000 ppm)</td><td>> 240 min</td></tr>
<tr><td>13</td><td>Carmustine, 3.3mg/mL (3,300 ppm)</td><td>40 min</td></tr>
<tr><td>14</td><td>Thiotepa, 10mg/mL (10,000 ppm)</td><td>88.6 min</td></tr>
<tr><th>No.</th><th>Non-chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr>
<tr><td>1</td><td>Fentanyl Citrate Injection, 100mcg/2mL</td><td>> 240min</td></tr>
<tr><td>2</td><td>Simulated Gastric Acid Fluid / Fentanyl Citrate Injection Mix 50/50 Solution</td><td>> 240min</td></tr>
</table>
The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:
Carmustine 3.3mg/mL (3,300 ppm), breakthrough detected at 40 minutes
Thiotepa 10mg/mL (10,000 ppm), breakthrough detected at 88.6 minutes

Warning: Not for use with Carmustine and Thiotepa.
</td>
<td>
<table>
<tr><th>No.</th><th>Chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr>
<tr><td>1</td><td>Cisplatin, 1mg/mL (1,000 ppm)</td><td>> 240min</td></tr>
<tr><td>2</td><td>Cyclophosphamide (Cytoxan), 20mg/mL (20,000 ppm)</td><td>> 240min</td></tr>
<tr><td>3</td><td>Dacarbazine (DTIC), 10mg/mL (10,000 ppm)</td><td>> 240min</td></tr>
<tr><td>4</td><td>Doxorubicin HCl (Adriamycin), 2mg/mL (2,000 ppm)</td><td>> 240min</td></tr>
<tr><td>5</td><td>Etoposide (Toposar), 20mg/mL (20,000 ppm)</td><td>> 240min</td></tr>
<tr><td>6</td><td>Fluorouracil (5 Flu), 50mg/mL (50,000 ppm)</td><td>> 240min</td></tr>
<tr><td>7</td><td>Ifosfamide (IFEX), 50mg/mL (50,000 ppm)</td><td>> 240min</td></tr>
<tr><td>8</td><td>Methotrexate, 25mg/mL (25,000 ppm)</td><td>> 240min</td></tr>
<tr><td>9</td><td>Mitomycin C, 0.5 mg/mL (500 ppm)</td><td>> 240min</td></tr>
<tr><td>10</td><td>Mitoxantrone HCl, 2mg/mL (2,000 ppm)</td><td>> 240min</td></tr>
<tr><td>11</td><td>Paclitaxel (Taxol), 6mg/mL (6,000 ppm)</td><td>> 240min</td></tr>
<tr><td>12</td><td>Vincristine Sulphate, 1mg/mL (1,000 ppm)</td><td>> 240 min</td></tr>
<tr><td>13</td><td>Carmustine, 3.3mg/mL (3,300 ppm)</td><td>40 min</td></tr>
<tr><td>14</td><td>Thiotepa, 10mg/mL (10,000 ppm)</td><td>88.6 min</td></tr>
<tr><th>No.</th><th>Non-chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr>
<tr><td>1</td><td>Fentanyl Citrate Injection, 100mcg/2mL</td><td>> 240min</td></tr>
<tr><td>2</td><td>Simulated Gastric Acid Fluid / Fentanyl Citrate Injection Mix 50/50 Solution</td><td>> 240min</td></tr>
</table>
The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:
Carmustine 3.3mg/mL (3,300 ppm), breakthrough detected at 40 minutes
Thiotepa 10mg/mL (10,000 ppm), breakthrough detected at 88.6 minutes

Warning: Not for use with Carmustine and Thiotepa
</td>
<td>
The following chemotherapy drugs and concentration had NO breakthrough detected up to 240 minutes:

Cisplatin (1 mg/ml)
Cyclophosphamide (20 mg/ml)
Dacarbazine (10 mg/ml)
Doxorubicin HCl (2 mg/ml)
Etoposide (20 mg/ml)
Fluorouracil (50 mg/ml)
Ifosfamide (50 mg/ml)
Methotrexate (25 mg/ml)
Mitomycin C (0.5 mg/ml)
Mitoxantrone HCl (2 mg/ml)
Paclitaxel (6 mg/ml)
Vincristine Sulfate (1 mg/ml)
Fentanyl Citrate Injection (100 mcg/2 mL)
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

The following chemotherapy drugs and concentration showed breakthrough detected in less than 90 minutes:
Carmustine (3.3 mg/ml), breakthrough detected at 55.2 minutes

Thiotepa (10 mg/ml), breakthrough detected at 88.6 minutes

Warning: Not for use with Carmustine and Thiotepa.
</td>
<td></td>
</tr>
<tr><td>Material</td><td>Nitrile</td><td>Nitrile</td><td>Nitrile</td><td>SAME</td></tr>
<tr><td>Powder or Powder Free</td><td>Powder Free</td><td>Powder Free</td><td>Powder Free</td><td>SAME</td></tr>
<tr><td>Color</td><td>Blue</td><td>Blue</td><td>Blue</td><td>SAME</td></tr>
<tr><td>Single use</td><td>Single use</td><td>Single use</td><td>Single use</td><td>SAME</td></tr>
</table>

Biocompatibility	Acute Systemic Toxicity ISO 10993-11:2017 Skin Sensitization ISO 10993-10: 2010 Irritation ISO 10993-10: 2010	Acute Systemic Toxicity ISO 10993-11:2017 Skin Sensitization ISO 10993-10: 2010 Irritation ISO 10993-10: 2010	Acute Systemic Toxicity ISO10993-11:2017 Skin Sensitization ISO 10993-10: 2010 Irritation ISO 10993-10: 2010	SAME
Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid Claim	Refer to Table 3	Refer to Table 3	Refer to Table 3	Analysis 1

Table 2 Technological Characteristic Comparison

Technological Characteristics	**Proposed Device (K262014)**		**Predicate Device (K220547)**	SAME
	PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves	PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves	PureZero MARIN Nitrile Powder-Free Exam Gloves, PureZero MARIN-XTRA Nitrile Powder-Free Exam Gloves	
Physical Dimension:				
Length	Minimum 240mm (9.5-inch)	Minimum 295mm (12-inch length)	Minimum 240 for MARIN Minimum 295mm for MARIN-XTRA	SAME
Palm Width (size) (mm):				
XS	60-80	60-80	60-80	SAME
S	70-90	70-90	70-90	SAME
M	85-105	85-105	85-105	SAME
L	100-120	100-120	100-120	SAME
XL	110-130	110-130	110-130	SAME
Thickness (mm):				
Finger	Minimum 0.1	Minimum 0.1	Minimum 0.1	SAME
Palm	Minimum 0.08	Minimum 0.08	Minimum 0.08	SAME
Tensile Strength, Before Aging	14MPa, min	14MPa, min	14MPa, min	SAME
Ultimate Elongation, Before Aging	500%, min	500%, min	500%, min	SAME
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	14MPa, min	SAME
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	400%, min	SAME
Watertight (1000ml)	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	SAME
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	≤ 2 mg per glove	SAME

Table 3 Chemotherapy Permeation and Fentanyl Citrate Comparison

Tested Chemotherapy Drug, Fentanyl Citrate and Gastric Acid Fluid	**Minimum BDT (Minutes)**		
	Proposed Device (K262014)		**Predicate Device (K220547)**
	PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves	PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves	PureZero MARIN Nitrile Powder-Free Exam Gloves, PureZero MARIN-XTRA Nitrile Powder-Free Exam Gloves
Cisplatin, 1mg/mL (1,000 ppm)	> 240min	> 240min	> 240min
Cyclophosphamide (Cytoxan), 20mg/mL (20,000 ppm)	> 240min	> 240min	> 240min
Dacarbazine (DTIC), 10mg/mL (10,000 ppm)	> 240min	> 240min	> 240min
Doxorubicin HCI (Adriamycin), 2mg/mL (2,000 ppm)	> 240min	> 240min	> 240min
Etoposide (Toposar), 20mg/mL (20,000 ppm)	> 240min	> 240min	> 240min
Fluorouracil (5 Flu), 50mg/mL (50,000 ppm)	> 240min	> 240min	> 240min
Ifosfamide (IFEX), 50mg/mL (50,000 ppm)	> 240min	> 240min	> 240min
Methotrexate, 25mg/mL (25,000 ppm)	> 240min	> 240min	> 240min
Mitomycin C, 0.5 mg/mL (500 ppm)	> 240min	> 240min	> 240min
Mitoxantrone HCI, 2mg/mL (2,000 ppm)	> 240min	> 240min	> 240min
Paclitaxel (Taxol), 6mg/mL (6,000 ppm)	> 240min	> 240min	> 240min
Vincristine Sulphate, 1mg/mL (1,000 ppm)	> 240 min	> 240 min	> 240 min
Carmustine, 3.3mg/mL (3,300 ppm)	40 min	40 min	55.2 min
Thiotepa, 10mg/mL (10,000 ppm)	88.6 min	88.6 min	88.6 min
Fentanyl Citrate Injection, 100mcg/2mL	> 240 min	> 240 min	> 240 min
Simulated Gastric Acid Fluid / Fentanyl Citrate Injection Mix 50/50 Solution	> 240 min	> 240 min	> 240 min

Analysis #1:

Chemotherapy drugs Fentanyl Citrate and Gastric Acid Fluid - the minimum breakthrough time of subject device was updated based on aged glove testing, which will be reflected in the product labeling when it appears to be in worst-case value. The revised labeling provides a conservative representation of product performance throughout the claimed shelf life and serves as a risk mitigation measure to ensure users are informed of the lowest observed breakthrough time during testing, so this difference does not raise questions of safety and effectiveness.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ASTM D6319-19:2023, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6124-06:2022, Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-19:2023, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6978-05:2023 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ASTM D7160-16 (Reapproved 2023), Standard Practice for Determination of Expiration Dating for Medical Gloves
- ISO 10993-11: 2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-10: 2020, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319-19	Physical Dimensions Length	MARIN* - Min 240mm MARIN-XTRA* - Min 295mm	Pass
ASTM D6319-19	Physical Dimensions Palm Width	Minimum: XS:60-80mm, S:70-90mm, M:85-105mm, L: 100-120mm, XL:110-130mm,	Pass
ASTM D6319-19	Physical Dimensions Thickness	Finger: 0.1mm (min) Palm: 0.08mm (min)	Pass
ASTM D6319-19	Physical Properties	Tensile Strength (Min 14MPa) and Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319- 19 ASTM D5151-19	Water leak test	AQL 2.5 (ISO 2859-1)	Pass
ASTM D6319- 19 ASTM D6124-06	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05	Permeation by Chemotherapy Drugs	Refer above table	Pass
ISO 10993-11	Acute systemic toxicity study	Under the conditions of the study, the device extract does not induce acute systemic toxicity response.	Pass
ISO 10993-10	Skin sensitization	Under the condition of the study, the device is not a sensitizer	Pass
ISO 10993-10	Irritation	Under the condition of the study, the device is not an irritant	Pass

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K220547).