DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K183287

Device Name

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*

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

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) (3.3 mg/ml)	10.1
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240
Cytarabine(100 mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Paclitaxel (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	30.2
Vincristine Sulfate (1.0 mg/ml)	>240

Please note that Carmustine (BCNU) has extremely low permeation times of 10.1 minutes.

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

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)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
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510(k) Number *(if known)*

K183287

Device Name

Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*

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

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) (3.3 mg/ml)	10.1
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240
Cytarabine(100 mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Paclitaxel (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	10.4
Vincristine Sulfate (1.0 mg/ml)	>240

Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU): 10.1 minutes and Thiotepa: 10.4 minutes

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

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)

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510(k) Number *(if known)*

K183287

Device Name

Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*

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

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) (3.3 mg/ml)	14.4
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240
Cytarabine(100 mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Paclitaxel (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	29.2
Vincristine Sulfate (1.0 mg/ml)	>240

Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU): 14.4 minutes and Thiotepa: 29.2 minutes

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

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)

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