

**Traditional 510(k) Notification (Bundled):  
Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Gloves - 12" Pairs**

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**Section 5 - 510(k) Summary**

<b>Preparation Date:</b>	July 06, 2010
<b>Applicant:</b>	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
<b>Contact Person:</b>	Lester F. Padilla Tel. No.: 678-352-6766
<b>Trade/Proprietary Name(s):</b>	Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves - 12" Pairs
<b>Common Name(s):</b>	Powder-Free Nitrile Patient Examination Gloves (Sterile)
<b>Classification Name:</b>	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

**Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:**

1. Safeskin Sterile PURPLE NITRILE\* Examination Gloves (Powder-Free) - K992062
2. Safeskin PURPLE\* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

**Device Description(s):**

Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Gloves are 12-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. The gloves are packaged as two gloves per sterile pouch.

**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Gloves - 12" Pairs**

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**Intended Use(s):**

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.

**Summary of Technologies:**

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

**Non-Clinical Testing:**

<b>Characteristics</b>	<b>Applicable FDA-Recognized Standards</b>	<b>Performance Results</b>
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements

**Clinical Testing:**

No Clinical testing was required to determine substantial equivalence of these devices.

**Conclusion:**

The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

**Traditional 510(k) Notification (Bundled):  
Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves - 9.5" Pairs**

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**Section 5 - 510(k) Summary**

<b>Preparation Date:</b>	July 06, 2010
<b>Applicant:</b>	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
<b>Contact Person:</b>	Lester F. Padilla Tel. No.: 678-352-6766
<b>Trade/Proprietary Name(s):</b>	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves – 9.5" Pairs
<b>Common Name(s):</b>	Powder-Free Nitrile Patient Examination Glove (Sterile)
<b>Classification Name:</b>	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

**Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:**

1. Safeskin Sterile PURPLE NITRILE\* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE\* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

**Device Description(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves are 9.5-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. The gloves are packaged as two gloves per sterile pouch.

**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves - 9.5" Pairs**

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**Intended Use(s):**

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.

**Summary of Technologies:**

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

**Non-Clinical Testing:**

<b>Characteristics</b>	<b>Applicable FDA-Recognized Standards</b>	<b>Performance Results</b>
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10  ISO 10993, Part 5	Meets ASTM Requirements

**Clinical Testing:**

No Clinical testing was required to determine substantial equivalence of these devices.

**Conclusion:**

The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

**Traditional 510(k) Notification (Bundled):  
Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves - 9.5 Singles**

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**Section 5 - 510(k) Summary**

<b>Preparation Date:</b>	July 06, 2010
<b>Applicant:</b>	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
<b>Contact Person:</b>	Lester F. Padilla Tel. No.: 678-352-6766
<b>Trade/Proprietary Name(s):</b>	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves – 9.5” Singles
<b>Common Name(s):</b>	Powder-Free Nitrile Patient Examination Glove (Sterile)
<b>Classification Name:</b>	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

**Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:**

1. Safeskin Sterile PURPLE NITRILE\* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE\* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

**Device Description(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves are 9.5-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. The gloves are packaged as one glove per sterile pouch.

**Traditional 510(k) Notification (Bundled):  
Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves - 9.5 Singles**

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**Intended Use(s):**

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.

**Summary of Technologies:**

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

**Non-Clinical Testing:**

<b>Characteristics</b>	<b>Applicable FDA-Recognized Standards</b>	<b>Performance Results</b>
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10  ISO 10993, Part 5	Meets ASTM Requirements

**Clinical Testing:**

No Clinical testing was required to determine substantial equivalence of these devices.

**Conclusion:**

The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 12” Pairs**

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**Section 5 - 510(k) Summary**

<b>Preparation Date:</b>	August 18, 2010
<b>Applicant:</b>	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
<b>Contact Person:</b>	Lester F. Padilla Tel. No.: 678-352-6766
<b>Trade/Proprietary Name(s):</b>	Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 12” Pairs
<b>Common Name(s):</b>	Powder-Free Nitrile Patient Examination Chemotherapy Use Glove (Sterile)
<b>Classification Name:</b>	Patient Examination Glove (21 CFR Part 880.6250), Patient Examination Glove, Specialty (Product Code LZC)

**Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:**

1. Safeskin Sterile PURPLE NITRILE\* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE\* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

**Device Description(s):**

Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) are 12-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. In addition these gloves were tested for use with the drugs listed in the Intended Use(s) section below, per ASTM D6978-05 “*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*” The gloves are packaged as two gloves per sterile pouch.

**K102032**

**Traditional 510(k) Notification (Bundled):  
Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Gloves  
(Chemotherapy Glove) – 12” Pairs**

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**Intended Use(s):**

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.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes:  
Carmustine (3.3 mg/ml) 48.6 minutes

**Summary of Technologies:**

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE-XTRA<sup>®</sup> Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 12” Pairs**

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**Non-Clinical Testing:**

<b>Characteristics</b>	<b>Applicable FDA-Recognized Standards</b>	<b>Performance Results</b>
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and/or ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

**Clinical Testing:**

No Clinical testing was required to determine substantial equivalence of these devices.

**Conclusion:**

The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 9.5" Pairs**

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**Section 5 - 510(k) Summary**

<b>Preparation Date:</b>	August 18, 2010
<b>Applicant:</b>	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
<b>Contact Person:</b>	Lester F. Padilla Tel. No.: 678-352-6766
<b>Trade/Proprietary Name(s):</b>	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 9.5" Pairs
<b>Common Name(s):</b>	Powder-Free Nitrile Patient Examination Chemotherapy Use Glove (Sterile)
<b>Classification Name:</b>	Patient Examination Glove (21 CFR Part 880.6250), Patient Examination Glove, Specialty (Product Code LZC)

**Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:**

1. Safeskin Sterile PURPLE NITRILE\* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE\* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

**Device Description(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) are 9.5-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. In addition these gloves were tested for use with the drugs listed in the Intended Use(s) section below, per ASTM D6978-05 "*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*." The gloves are packaged as two gloves per sterile pouch.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 9.5” Pairs**

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**Intended Use(s):**

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.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes:  
Carmustine (3.3 mg/ml) 48.6 minutes

**Summary of Technologies:**

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 9.5” Pairs**

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**Non-Clinical Testing:**

<b>Characteristics</b>	<b>Applicable FDA-Recognized Standards</b>	<b>Performance Results</b>
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and/or ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

**Clinical Testing:**

No Clinical testing was required to determine substantial equivalence of these devices.

**Conclusion:**

The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 9.5” Singles**

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**Section 5 - 510(k) Summary**

<b>Preparation Date:</b>	August 18, 2010
<b>Applicant:</b>	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
<b>Contact Person:</b>	Lester F. Padilla Tel. No.: 678-352-6766
<b>Trade/Proprietary Name(s):</b>	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 9.5” Single
<b>Common Name(s):</b>	Powder-Free Nitrile Patient Examination Chemotherapy Use Glove (Sterile)
<b>Classification Name:</b>	Patient Examination Glove (21 CFR Part 880.6250), Patient Examination Glove, Specialty (Product Code LZC)

**Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:**

1. Safeskin Sterile PURPLE NITRILE\* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE\* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

**Device Description(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) are 9.5-inch long; sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. In addition these gloves were tested for use with the drugs listed in the Intended Use(s) section below, per ASTM D6978-05 “*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*.” The gloves are packaged as one glove per sterile pouch.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 9.5" Singles**

---

**Intended Use(s):**

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.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
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Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes:  
 Carmustine (3.3 mg/ml) 48.6 minutes

**Summary of Technologies:**

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

**K102032**  
**Traditional 510(k) Notification (Bundled):**  
**Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Gloves**  
**(Chemotherapy Glove) – 9.5” Singles**

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**Non-Clinical Testing:**

<b>Characteristics</b>	<b>Applicable FDA-Recognized Standards</b>	<b>Performance Results</b>
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and/or ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

**Clinical Testing:**

No Clinical testing was required to determine substantial equivalence of these devices.

**Conclusion:**

The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Kimberly-Clark Corporation  
C/O Mr. Ned Divine  
Responsible Third Party Official  
Underwriters Laboratories, Incorporated  
333 Pfingsten Road  
Northbrook, Illinois 60062

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

SEP 08 2010

Re: K102032

Trade/Device Name: Kimberly-Clark Purple NITRILE-XTRA \*Sterile Powder-Free Examination Glove with Tested For Use with Chemotherapy Drug Labeling Claim (12"Pairs)  
Labeling Claim (12"Pairs).  
Kimberly-Clark Purple NITRILE Sterile Powder-Free Examination Glove with Tested For Use with Chemotherapy Labeling Claim (9.5"Pairs)  
Kimberly-Clark Purple NITRILE Sterile Powder Free Examination Glove with Tested For Use with Chemotherapy Drug Labeling Claim (9.5"Single)  
Kimberly-Clark Purple NITRILE-XTRA \*Sterile Powder-Free Examination Glove (12"Pairs)  
Kimberly-Clark Purple NITRILE \*Sterile Powder-Free Examination Glove (9.5"Pairs)  
Kimberly-Clark Purple NITRILE\* Sterile Powder-Free Examination Glove (9.5"Single)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA, LZC

Dated: August 18, 2010

Received: August 20, 2010

Dear Mr. Devine:

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.

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.

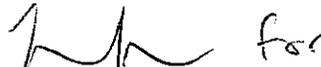
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Glove  
(Chemotherapy Glove) – 12” Pairs

**Indications for 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.

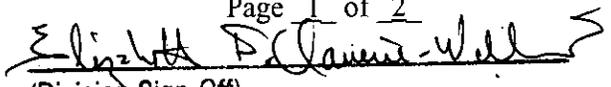
In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 48.6 minutes

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(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K102032

**Indications for Use (cont'd)**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Glove  
(Chemotherapy Glove) – 12” Sterile Pairs

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use  X   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:  K102032

### Indications for Use

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Glove  
(Chemotherapy Glove) – 9.5” Pairs

**Indications for 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.

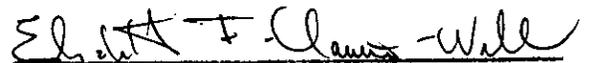
In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 48.6 minutes

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Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K102032

**Indications for Use (cont'd)**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Glove  
(Chemotherapy Glove) – 9.5” Sterile Pairs

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use   X    
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K 102032

**Indications for Use**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Glove  
(Chemotherapy Glove) – 9.5” Singles

**Indications for 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.

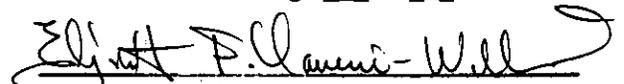
In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 48.6 minutes

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Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K102032

**Indications for Use (cont'd)**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Glove  
(Chemotherapy Glove) – 9.5” Sterile Single

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use   X    
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K102032

**Indications for Use**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE-XTRA\* Sterile Powder-Free Exam Glove  
(12" Pairs)

**Indications for 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.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

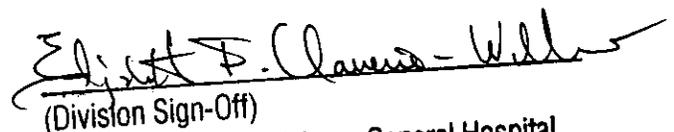
Over-The-Counter Use X  
(21 CFR 801 Subpart C)

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Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K102032

**Indications for Use**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Glove  
(9.5" Pairs)

**Indications for 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.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

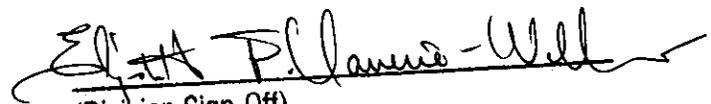
AND/OR

Over-The-Counter Use X  
(21 CFR 801 Subpart C)

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Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K102032

**Indications for Use**

510(k) Number (if known): K102032

**Device Name(s):**

Kimberly-Clark PURPLE NITRILE\* Sterile Powder-Free Exam Glove  
(9.5" Singles)

**Indications for 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.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

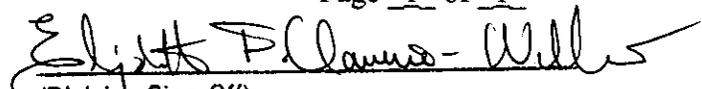
Over-The-Counter Use X  
(21 CFR 801 Subpart C)

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510(k) Number: K102032