K101596

Kimberly-Clark Corporation

JUL 21 2010

Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (Chemotherapy)

Section 5 - 510(k) Summary

Preparation Date:	30 June 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (Chemotherapy Glove)
Common Name(s):	Powder-Free Nitrile Patient Examination Chemotherapy Use Gloves
Classification Name:	Patient Examination Glove, Specialty (21 CFR Part 880.6250 - Product Code LZC)

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

1. Safeskin Purple Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
2. Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-XTRA* Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
3. Kimberly-Clark LAVENDER* Nitrile Powder-Free Examination Glove - K081260

Device Description(s):

Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (Chemotherapy Glove) are 12-inch long, non-sterile purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D6319-00a, *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."*

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:

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Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (Chemotherapy)

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

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

The following drugs showed breakthrough detected in less than 30 minutes:

Carmustine (3.3mg/ml): 1.8 minutes	ThioTEPA (10.0mg/ml): 1.7 minutes

Warning – Not for Use with Carmustine and ThioTEPA

Summary of Technologies:

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

Non-Clinical Testing (Subject Device):

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D6319-00a ASTM D5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D6319-00a ASTM D6124-06	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 D6978-05 and/or ASTM F739-07	Meets ASTM Requirements See Intended Use Section for Device 1

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Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (Chemotherapy)

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Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (Chemotherapy)

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.

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Kimberly-Clark Corporation

Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy)

Section 5 - 510(k) Summary

Preparation Date:	30 June 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy Glove)
Common Name(s):	Powder-Free Nitrile Patient Examination Chemotherapy Use Gloves
Classification Name:	Patient Examination Glove, Specialty (21 CFR Part 880.6250 - Product Code LZC)

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

1. Safeskin Purple Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
2. Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-XTRA* Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
3. Kimberly-Clark LAVENDER* Nitrile Powder-Free Examination Glove - K081260

Device Description(s):

Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy Glove) are 9.5-inch long, non-sterile purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D6319-00a, *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."*

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:

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Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy)

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

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

The following drugs showed breakthrough detected in less than 30 minutes:

Carmustine (3.3mg/ml): 1.8 minutes	ThioTEPA (10.0mg/ml): 1.7 minutes

Warning – Not for Use with Carmustine and ThioTEPA

Summary of Technologies:

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

Non-Clinical Testing (Subject Device):

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D6319-00a ASTM D5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D6319-00a ASTM D6124-06	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 D6978-05 and/or ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

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Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy)

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.

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Kimberly-Clark Corporation

Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves

Section 5 - 510(k) Summary

Preparation Date:	30 June 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves
Common Name(s):	Powder-Free Nitrile Patient Examination Gloves
Classification Name:	Polymer Patient Examination Glove (21 CFR Part 880.6250 - Product Code LZA)

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

1. Safeskin Purple Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
2. Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-XTRA* Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
3. Kimberly-Clark LAVENDER* Nitrile Powder-Free Examination Glove - K081260

Device Description(s):

Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves are 9.5-inch long, non-sterile purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

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.

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Kimberly-Clark Corporation

Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves

Non-Clinical Testing (Subject Device):

Characteristics	Applicable FDA-Recognized Standards	Performance Results
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.

K101596

Kimberly-Clark Corporation

Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves

Section 5 - 510(k) Summary

Preparation Date:	30 June 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves
Common Name(s):	Powder-Free Nitrile Patient Examination Gloves
Classification Name:	Polymer Patient Examination Glove (21 CFR Part 880.6250 - Product Code LZA)

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

1. Safeskin Purple Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
2. Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-XTRA* Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
3. Kimberly-Clark LAVENDER* Nitrile Powder-Free Examination Glove - K081260

Device Description(s):

Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves are 12-inch long, non-sterile purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

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.

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Kimberly-Clark Corporation

Traditional 510(k) Notification:
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves

Non-Clinical Testing (Subject Device):

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D6319-00a ASTM D5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D6319-00a ASTM D6124-06	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

JUL 21 2010

Re: K101596
Trade/Device Name: Kimberly –Clark PURPLE NITRILE* Powder-Free Exam Glove (Chemotherapy Gloves)
Kimberly –Clark PURPLE NITRILE –XTRA* Powder-Free Exam Glove (Chemotherapy Gloves)
Kimberly –Clark PURPLE NITRILE Powder-Free Exam Glove
Kimberly –Clark PURPLE NITRILE –XTRA* Powder-Free Exam Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC, LZA
Dated: July 2, 2010
Received: July 6, 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

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.

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,

for

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

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K101596

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy Gloves)

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

The following drugs showed breakthrough detected in less than 30 minutes:

Carmustine (3.3mg/ml): 1.8 minutes	ThioTEPA (10.0mg/ml): 1.7 minutes

Warning – Not for Use with Carmustine and ThioTEPA

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

510(k) Number: K101596

K101596

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K101596

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (Chemotherapy Gloves)

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:

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Cyclophosphamide (20 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Melphalan (5.0mg/ml)
Dacarbazine (10 mg/ml)	Methotrexate (25.0mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitomycin (0.5mg/ml)
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Warning – Not for Use with Carmustine and ThioTEPA

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

510(k) Number: k101596

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K101596

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K101596

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K101596

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K101596