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ANTI-COVID-19 PRODUCTS

KIMBERLY CLARK NITRILE EXAMINATION GLOVES

Products listed within this document are available for immediate shipment / delivery. Interested parties are encouraged to contact us via email: bizdev@freeworldbrand.com for pricing and other related information. NOTE: Principals Only.

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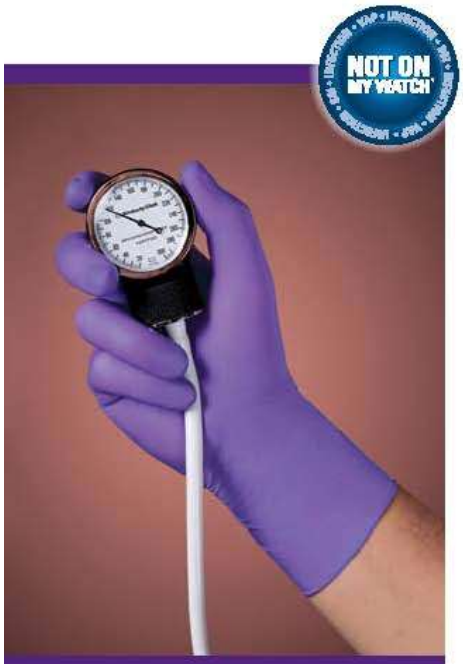
Web-Presence: http://freeworldbrand.com
Phone/Fax: 609-318-0570

KIMBERLY-CLARK® KC500 PURPLE NITRILE® Exam Gloves



Maximum Protection for Higher-Risk Procedures

KC500 PURPLE NITRILE® Exam Gloves have become the glove of choice in healthcare facilities nationwide to protect clinicians from bacteria, viruses, and chemicals during procedures where the risk of fluid exposure is moderate to high. These durable latex-free gloves are available in 9.5 and 12-inch lengths, for maximum coverage and protection, especially when dealing with unknown risks.

Trusted, Outstanding Barrier Performance

Healthcare professionals in the ER, ICU, and Oncology[1] Units of acute care facilities, as well as EMS staff, Dental clinicians, and Cancer Center specialists all rely on PURPLE Nitrile Exam Gloves. When they see that unique purple color, clinicians know they have protection they can trust, and that gives them the confidence to provide the best care to every patient.

KC500 PURPLE NITRILE® Exam Gloves are ideal for moderate to high risk settings, Purple Nitrile is a highly durable synthetic, eliminating the problem of exposure to latex exam gloves while maximizing protection.

KC500 PURPLE NITRILE® GLOVES

Testing with 12 chemotherapy drugs (7 required and 5 additional widely used drugs) under conditions of continuous contact, intended to approximate the worst case condition for clinical use (ASTM Test Method F739), proved that PURPLE Nitrile provides barrier protection against permeation of all 12 drugs.

Tell your Kimberly-Clark Sales Representative you want the durable feel and demonstrated performance of KC500 PURPLE NITRILE® Exam Gloves.

KC500

Kimberly-Clark
Trusted Clinical Solutions®

KIMBERLY-CLARK® KC500 PURPLE NITRILE® Exam Gloves

Clinical Considerations

Natural rubber latex-free – primary material is acrylonitrile/butadiene, reducing the potential for glove-associated Type I allergic reactions to natural rubber latex proteins

Powder-free, minimizing the potential for powder-related complications, such as irritant contact dermatitis

Quality Standards

Exceeds current ASTM D 6319 standard for critical defects (AQL-2.5). AQL for critical defects is 1.5.

Manufactured in accordance with Quality System ISO 9001:2000.

Biocompatible as measured by Primary Skin Irritation, Repeat Challenge Sensitization and 200 Person Modified Draize Test.

Sterilized in accordance with AAMI guidelines at a Sterility Assurance Level (SAL) of 10^{-6}.

1. Purple Nitrile-Xtra material has been tested for use with twelve chemotherapy drugs and glutaraldehyde to determine permeation and breakthrough times. Test results on file.

The Kimberly-Clark Advantage

Knowledge Network® Accredited Education
Ongoing Customer Support
Expert Sales Force
Tools & Best Practices
Clinical Research
Commitment to Excellence

Infection prevention website:
www.HAIwatch.com

For more information, please call your sales representative, or visit our Web site at www.kchealthcare.com.

Product Ordering Information

LATEX FREE

KIMBERLY-CLARK® KC500 PURPLE NITRILE® Exam Gloves - 9.5"

Item#	Description	Size	Packaging
55080	KC500 Purple Nitrile® Powder-Free Exam Glove	X-Small	100 each/box 10 boxes/case
55081	KC500 Purple Nitrile® Powder-Free Exam Glove	Small	100 each/box 10 boxes/case
55082	KC500 Purple Nitrile® Powder-Free Exam Glove	Medium	100 each/box 10 boxes/case
55083	KC500 Purple Nitrile® Powder-Free Exam Glove	Large	100 each/box 10 boxes/case
55084	KC500 Purple Nitrile® Powder-Free Exam Glove	X-Large	90 each/box 10 boxes/case

KIMBERLY-CLARK® KC500 PURPLE NITRILE-XTRA® Exam Gloves - 12"

Item#	Description	Size	Packaging
50600	KC500 Purple Nitrile-Xtra® Powder-Free Exam Glove	X-Small	50 each/box 10 boxes/case
50601	KC500 Purple Nitrile-Xtra® Powder-Free Exam Glove	Small	50 each/box 10 boxes/case
50602	KC500 Purple Nitrile-Xtra® Powder-Free Exam Glove	Medium	50 each/box 10 boxes/case
50603	KC500 Purple Nitrile-Xtra® Powder-Free Exam Glove	Large	50 each/box 10 boxes/case
50604	KC500 Purple Nitrile-Xtra® Powder-Free Exam Glove	X-Large	50 each/box 10 boxes/case

KIMBERLY-CLARK® KC500 PURPLE NITRILE® Sterile Single and Pairs Exam Gloves - 9.5"

Item#	Description	Size	Packaging
52101	KC500 Purple Nitrile® Sterile Single Exam Gloves	Small	100 gloves/box 4 boxes/case
52102	KC500 Purple Nitrile® Sterile Single Exam Gloves	Medium	100 gloves/box 4 boxes/case
52103	KC500 Purple Nitrile® Sterile Single Exam Gloves	Large	100 gloves/box 4 boxes/case
55091	KC500 Purple Nitrile® Sterile Pairs Exam Gloves	Small	50 pairs/box 4 boxes/case
55092	KC500 Purple Nitrile® Sterile Pairs Exam Gloves	Medium	50 pairs/box 4 boxes/case
55093	KC500 Purple Nitrile® Sterile Pairs Exam Gloves	Large	50 pairs/box 4 boxes/case

Product Specifications

Gauge Thickness Measurements	MM	MIL
Middle Finger:	.15	5.9
Palm:	.12	4.7
Cuff:	.09	3.5

Average Length	
	242mm (9.5")
Xtra®	305mm (12.0")

Physical Properties

Before Aging	
Tensile Strength:	21 MPa
Ultimate Elongation:	550%

After Aging	
Tensile Strength:	21 MPa
Ultimate Elongation:	500%

Kimberly-Clark
Trusted Clinical Solutions®

Kimberly-Clark PROFESSIONAL®

TECHNICAL DATA SHEET

www.kimtech.com
800-255-6401

KIMBERLY-CLARK® STERLING® Nitrile Exam Glove Test Method and Claim Summary

TEST & TECHNICAL DATA	Test	Objective	Relevance	FDA Requirement	ASTM Requirement	Kimberly-Clark Requirement	Descriptions	STERLING® Results/Target
	ASTM D5151 Detection of Holes in Medical Gloves (Water Leak)	Determine acceptability of gloves with respect to freedom from holes. The lower the Acceptance Quality Level (AQL), the better.	Measures potential for glove barrier integrity failure using ASTM standards.	4.0 AQL	2.5 AQL	1.5 AQL		Pass @ 1.5 AQL
	ASTM D412 Standard Test method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (Tensile Strength)'	To assess the amount of force applied to a glove until it breaks. The lower the Acceptance Quality Level (AQL), the better.	The lower the tensile strength, the more easily materials of the same thickness can break when snagged or pressure is applied.	4.0 AQL	4.0 AQL	2.5 AQL	Before Aging After Aging	42 MPa 30 MPa
	ASTM D412 Standard Test method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (Ultimate Elongation)	The ability to stretch a glove until it breaks. The lower the Acceptance Quality Level (AQL), the better.	Stretchability is very important at the microscopic level where the glove material must be able to give rather than break when stressed or snagged by instruments, fingernails, edges on caps, twisting stop cocks on IV sets, or snapping off enclosures.	4.0 AQL	4.0 AQL	2.5 AQL	Before Aging After Aging	650% 550%
	ASTM D3767 Standard Practice for Rubber Measurement of Dimensions (Thickness)	Thickness is measured in millimeters (mm) utilizing a micrometer at specified locations on the finger, palm and cuff. The lower the Acceptance Quality Level (AQL), the better.	Thickness is a metric that can be used in determining both tactile sensitivity and barrier protection. Consistency for this metric is key for both durability and chemical permeation protection.	4.0 AQL	4.0 AQL	2.5 AQL	Finger Palm Cuff	0.09 mm 0.08 mm 0.07 mm
	ASTM D3767 Standard Practice for Rubber Measurement of Dimensions (Length)	Length is measured in millimeters (mm) utilizing a ruler or tape from the upper finger tip to cuff. The lower the Acceptance Quality Level (AQL), the better.	This measurement helps ensure appropriate length and size correctness.	4.0 AQL 230 mm	4.0 AQL 230 mm	2.5 AQL 232 mm	U.S.	2.5 AQL 242 mm
	ASTM D6124 Residual Powder on Medical Gloves	Determine amount of residual powder on the glove surface; ASTM specifies the maximum allowed level of filter-retained substances for a powder-free claim.	A powder free glove helps reduce powder-associated wound healing complications caused by starch glove powder and helps reduce irritant reactions and the transfer of proteins and chemicals that could potentially result in Type IV or I reactions.	<2mg	<2mg	<2mg		<2mg; Pass
SYSTEM BIOCOMPATIBILITY	Systemic Toxicity ISO 10993-11	Evaluate the potential for harmful effects to organs or systems using specific product extracts.	Reduce risk of adverse systemic and local response due to contact with product.	Optional		Pass		Pass

KIMBERLY-CLARK® STERLING® Nitrile Powder Free Exam Gloves have been tested according to the tests listed above.

KIMTECH®

Kimberly-Clark PROFESSIONAL*

KIMBERLY-CLARK* STERLING* Nitrile Exam Glove Test Method and Claim Summary

TEST & TECHNICAL DATA	Test	Objective	Relevance	FDA Requirement	ASTM Requirement	Kimberly-Clark Requirement	Descriptions	STERLING* Results/Target
IRRITATION AND SENSITIZATION	Primary Skin Irritation ISO 10993-10	Estimate the potential to induce skin irritation from direct exposure.	Measures the likelihood of dermal irritation from contact with the product.	Pass		Pass		Pass
	Sensitization ISO 10993-10	Estimate the potential to induce contact sensitization Type IV delayed hypersensitivity immunological response via product extracts.	Decrease the likelihood of adverse immunological dermal response from product use over time.	Yes		Pass		Pass
RESIDUAL CHEMICALS	High Pressure Liquid Chromatography (HPLC)	Measure the type and amount of residual chemicals left on the glove.	Lower levels of residual chemicals decrease the risk of developing irritant and Type IV reactions.	Optional		Pass		Pass
VIRAL PENETRATION	Penetration by Bloodborne Pathogens Using Phi X174 Bacteriophage (Viral Penetration) ASTM F1671-97b	Measure the resistance of materials used in protective apparel to penetration by bloodborne pathogens.	Measures resistance to potentially infectious body fluids permeating through the protective material.	Pass		Pass		Pass
BARRIER	Resistance of Protective Materials to permeation by Liquids ASTM F739	Determine the level of barrier protection to chemicals which are commonly used in a laboratory environment.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.					Specific breakthrough times on record

KIMBERLY-CLARK* STERLING* Nitrile Powder-Free Exam Gloves have been tested according to the tests listed above.

Tested Chemotherapy Drug and Concentration	Average Breakthrough Detection Time (Minutes)
Cyclophosphamide (20.0 mg/ml)	No breakthrough up to 240 minutes
Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
5-Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
Paclitaxel (Taxol) (6.0 mg/ml)	No breakthrough up to 240 minutes
Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
Dacarbazine (10 mg/ml)	No breakthrough up to 240 minutes
Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
Carmustine (3.3 mg/ml)	Not for Use with Carmustine
ThioTEPA (10.0 mg/ml)	Not for Use with ThioTEPA

The STERLING and STERLING NITRILE-XTRA* Powder-Free Exam Glove material was tested with the above chemotherapy drug concentrations in accordance with ASTM D 6978, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

CAUTION: *The testing conditions used are intended to approximate the worst case conditions for clinical use. Testing was conducted on single layer glove material. It is the users' responsibility to determine the applicability of these gloves for their intended use with chemotherapy drugs.*

K113423

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Kimberly-Clark Corporation

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

Section 5 - 510(k) Summary

Preparation Date:	February 14, 2012
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 – 9.5"
Common Name(s):	Powder-Free Nitrile Patient Examination Glove
Classification Name:	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. **K102032**: Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Singles); Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (12" Pairs); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Singles);
2. **K101596:** Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy Gloves – 12"); Kimberly-Clark PURPLE NITRILE * Powder-Free Exam Glove (Chemotherapy Gloves – 9.5"); Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5");

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 the specifications of ASTM D 6319-10, *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.

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE® Powder-Free Exam Gloves - 9.5" Length

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10	Meets ASTM Requirements
Physical Properties	ASTM D 6319-10	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-10 ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-10 ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Systemic Toxicity Study	ISO 10993, Part 10 ISO 10993, Part 11	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.

K113423

Kimberly-Clark Corporation

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

Section 5 - 510(k) Summary

Preparation Date:	February 14, 2012
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 – 12" Length
Common Name(s):	Powder-Free Nitrile Patient Examination Gloves
Classification Name:	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. **K102032**: Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Singles); Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (12" Pairs); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Singles);
2. **K101596:** Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy Gloves – 12"); Kimberly-Clark PURPLE NITRILE * Powder-Free Exam Glove (Chemotherapy Gloves – 9.5"); Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5");

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 the specifications of ASTM D 6319-10, *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.

K113423

Kimberly-Clark Corporation

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

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10	Meets ASTM Requirements
Physical Properties	ASTM D 6319-10	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-10 ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-10 ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Systemic Toxicity Study	ISO 10993, Part 10 ISO 10993, Part 11	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.

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12")
Tested for Use with Chemotherapy Drugs

Section 5 - 510(k) Summary

Preparation Date:	February 14, 2012
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 – 12" Length
Common Name(s):	Powder-Free Nitrile Patient Examination Glove – Tested for Use with Chemotherapy Drugs.
Classification Name:	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. **K102032**: Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Singles); Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (12" Pairs); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Singles);

2. **K101596**: Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5"); Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5");

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 the specifications of ASTM D 6319-10, *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."*

These gloves meet the 2008 Glove Guidance Manual recommended minimum thickness and length specifications for gloves tested for use with chemotherapy drugs.

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12")
Tested for Use with 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:

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

Bleomycin sulfate (15 mg/ml)	Gemcitabine HCl (38.0mg/ml)
Busulfan (6 mg/ml)	Idarubicin HCl (1.0mg/ml)
Carboplatin (10 mg/ml)	Ifosfamide (50.0 mg/ml)
Cisplatin (1.0 mg/ml)	Irinotecan HCl (20.0 mg/ml)
Cyclophosphamide (20.0 mg/ml)	Mechlorethamine HCl (1.0 mg/ml)
Cytarabine HCl (100 mg/ml)	Melphalan (5 mg/ml)
Dacarbazine (10 mg/ml)	Methotrexate (25 mg/ml)
Daunorubicin HCl (5.0 mg/ml)	Mitomycin-C (0.5 mg/ml)
Docetaxel (10.0 mg/ml)	Mitoxantrone (2.0 mg/ml)
Doxorubicin HCl (2.0 mg/ml)	Paclitaxel (6.0 mg/ml)
Epirubicin (Ellence) (2 mg/ml)	Rituximab (10 mg/ml)
Etoposide (20.0 mg/ml)	ThioTEPA (10.0 mg/ml)
Fludarabine (25 mg/ml)	Trisenox (0.1 mg/ml)
Fluorouracil (50.0 mg/ml)	Vincristine Sulfate (1.0 mg/ml)

Please note that the following drug has low permeation times of less than 60 minutes:
Carmustine (3.3 mg/ml) 30.7 minutes

Summary of Technologies:

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

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA® Powder-Free Exam Gloves (12")
Tested for Use with Chemotherapy Drugs

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10 and 2008 FDA Glove Guidance Manual (for thickness and length)	Meets ASTM Requirements and 2008 FDA Glove Guidance Manual (for thickness and length)
Physical Properties	ASTM D 6319-10	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-10 ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-10 ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Systemic Toxicity Study	ISO 10993, Part 10 ISO 10993, Part 11	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and 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

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

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

MAR - 9 2012

Re: K113423
Trade/Device Name: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Glove with Tested for Use with Chemotherapy Drugs Labeling Claim (12" Length)
Kimberly-Clark Purple NITRILE-XTRA* Powder-Free Exam Glove (12" Length)
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Length)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: February 23, 2012
Received: February 24, 2012

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.

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

K 11 3423

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K113423

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Glove With TesTed FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM – 12" Length

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 mg/ml)	Gemcitabine HCl (38.0mg/ml)
Busulfan (6 mg/ml)	Idarubicin HCl (1.0mg/ml)
Carboplatin (10 mg/ml)	Ifosfamide (50.0 mg/ml)
Cisplatin (1.0 mg/ml)	Irinotecan HCl (20.0 mg/ml)
Cyclophosphamide (20.0 mg/ml)	Mechlorethamine HCl (1.0 mg/ml)
Cytarabine HCl (100 mg/ml)	Melphalan (5 mg/ml)
Dacarbazine (10 mg/ml)	Methotrexate (25 mg/ml)
Daunorubicin HCl (5.0 mg/ml)	Mitomycin-C (0.5 mg/ml)
Docetaxel (10.0 mg/ml)	Mitoxantrone (2.0 mg/ml)
Doxorubicin HCl (2.0 mg/ml)	Paclitaxel (6.0 mg/ml)
Epirubicin (Ellence) (2 mg/ml)	Rituximab (10 mg/ml)
Etoposide (20.0 mg/ml)	ThioTEPA (10.0 mg/ml)
Fludarabine (25 mg/ml)	Trisenox (0.1 mg/ml)
Fluorouracil (50.0 mg/ml)	Vincristine Sulfate (1.0 mg/ml)

Please note that the following drug has low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 30.7 minutes

Elizabeth A. Claire Williams

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

510(k) Number: K113423

K 113423

Kimberly-Clark Corporation

Indications for Use (cont'd)

510(k) Number (if known): K 113423

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

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: K113423

K113423

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K113423

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Glove (12" Length)

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)

Elizabeth F. Claxton-Wilson

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

510(k) Number: K113423

K113423

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K113423

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Length)

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)

Elizabeth T. Claxton-Wells

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

510(k) Number: K113423

Page 1 of 1

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3PLY DISPOSABLE FACE MASK

CIF – LOS ANGELES, CALIFORNIA - (FYI ONLY)

PRODUCT: 3PLY Disposable Face Masks | Melt blown layer in the middle
Color : Blue and Black
Mask size: 17.5x9.5cm
Standard : GB/T 32610-2016

Test Report: attached
Certificate: FDA certificate (attached)

CIF LA Price (by sea) : *$1.75 per box* - (50pcs/box) for blue color.
$1.90 per box - (50pcs/box) for black color.

Package : 50pcs/Opp bag/inner box **|** 40 boxes/carton **|** 2000pcs/carton
Carton size : 565*420*340mm GW: 9.8KG
1x40 HQ Quantity : 68CBM=840 CTN=33600 boxes
Lead | Delivery Time: 22 days

DETAILS RELATED TO THIS LOT APPEAR ON THE FOLLOWING PAGES

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BLACK 3PLY MASK IMAGES

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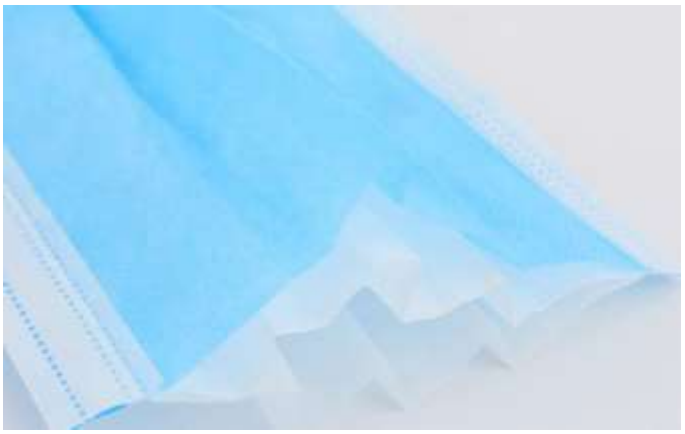
BLUE 3PLY MASK IMAGES



BOXES

CERTIFICATION | TEST REPORTS

- **Please Contact Us at: *bizdev@freeworldbrand.com***

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Become a **SUPPLIER** to FreeWorldImports. We are a **INVENTORY LIQUIDATION MARKETPLACE** with a growing customer base to include **domestic and international traders, merchants, governments and others** who have being working with us based on the long lasting relationships that we have cemented with them over the years. We are in the process of growing our supplier base and is constantly reaching out to **reputable supplier organizations** to join our supplier network.

As a supplier to our marketplace, you will be afforded the following:

1. Access to FreeWorldImports **global customer base**.
2. **Increased reach** - showcase your products within the FreeWorldImports member network.
3. **Access to the FreeWorldImports Supplier Portal** which provides the following;
   - **Capability to upload and list products** that are available for sale within the marketplace
   - **Monitor Earnings** - (Daily, Weekly, Monthly and Yearly sales activities)
   - **Collaborate** with FreeWorldImports Affiliates and Agents
   - Utilize FreeWorldImports link based engine to **socialize your listed products via Social Media and other digital mediums.**
4. **Get paid** fast for listed products that have been sold within the marketplace. Funds will be credited to your bank account within hours after a transaction is completed as opposed to days.

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