Kimberly-Clark* Purple Nitrile* Exam Gloves

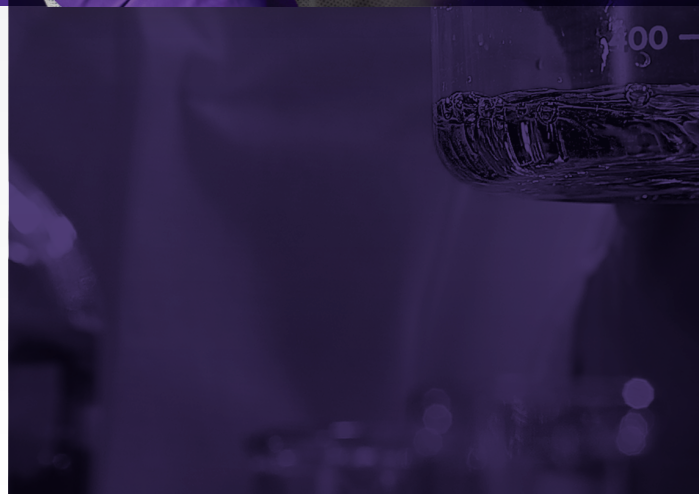
Put the Science of Protection to Work in Your Lab

Your employees are your most valuable asset. That's why they deserve the worry-free protection of Kimberly-Clark* Purple Nitrile* Exam Gloves. Our gloves guard against incidental splash exposure. The gloves are made of a highly durable nitrile polymer that eliminates the risks and costs associated with type 1 natural rubber latex allergies.

Kimberly-Clark* Purple Nitrile* Exam Gloves are the gloves of choice in leading labs because they are comfortable to wear and provide excellent tactile sensitivity. When users see the distinctive color purple, they know they can concentrate on the task at hand, protected from known and unknown risks.

Smartpull* Dispenser Box

Smartpull dispensing incorporates 2 separate openings on the box. The first, smaller opening is used when the box is full and helps control dispensing to lessen waste from dropped gloves or multiple dispensing. When the box is half empty, the second, larger opening allows easier access to the gloves. In addition, the dispensing box also provides up to a 33% waste savings.*



Kimberly-Clark PROFESSIONAL*

Exceptional Workplaces*

Kimberly-Clark* Purple Nitrile* Exam Glove Features and Specifications

- Latex-free, powder free
- Beaded cuff
- Ambidextrous
- Textured fingertips
- AQL 1.5
- 9.5" & 12" lengths
- Excellent dexterity and tactile sensitivity
- Comfortable fit
- Cleared for use in chemotherapy
- Available in Sterile and Non-Sterile
- Purple Nitrile-Xtra* Exam Gloves meet NFPA Standards 1999: 2008

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%

Quality Standards

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

Manufactured in accordance with Quality System ISO 9001.

Best Protection

When you're in the market for protection, turn to the proven leader. Kimberly-Clark* Purple Nitrile* Exam Gloves provide peace of mind for your lab personnel.

Kimberly-Clark* Purple Nitrile* Exam Gloves

Description	Color	X-Small	Small	Medium	Large	X-Large	Gloves/Boxes	Total/Case
Kimberly-Clark* Purple Nitrile* Exam Gloves 9.5" Ambi	Purple	**55080**	**55081**	**55082**	**55083**	**55084**	100/10 (XL - 90/10)	1000 (XL - 900)
Kimberly-Clark* Purple Nitrile-XTRA* Exam Gloves 12" Ambi	Purple	**55090**	**50601**	**50602**	**50603**	**50604**	50/10	500

Specific chemical resistance data can be found at: **www.kc-safety.com/chemicalbarrierdata**

Kimberly-Clark* Purple Nitrile* Sterile Exam Gloves

Description	Color	Small	Medium	Large	Gloves/Boxes	Total/Case
Kimberly-Clark* Purple Nitrile* Sterile Single Exam Gloves 9.5" Ambi	Purple	**52101**	**52102**	**52103**	100/4	400
Kimberly-Clark* Purple Nitrile* Sterile Pairs Exam Gloves 9.5" Ambi	Purple	**55091**	**55092**	**55093**	50 pairs/4	200 pairs

Good for your business, good for the planet.

RightCycle* from Kimberly-Clark Professional* is an innovative program that helps you mitigate waste and cross-contamination issues in current processes and reach Corporate Social Responsibility (CSR) and Sustainability goals.

No more downcycling or upcycling. RightCycle* makes it easy to recycle previously hard-to-recycle products like cleanroom garments and gloves into a variety of useful, eco-friendly products.

For more information, ask your distributor sales professional or contact Kimberly-Clark Professional* directly at 800-255-6401.

RightCycle* by KIMBERLY-CLARK PROFESSIONAL*

Our Guarantee

Your total satisfaction means everything to us. If, for any reason, our products do not meet your expectations, Kimberly-Clark will reimburse you‡ for your initial purchase, via FREE product, for up to $1,000. For more information on Kimberly-Clark Professional*, visit us online at **www.kcprofessional.com**, contact your Kimberly-Clark Sales Representative, or call us at 1-888-346-GOKC (4652).

‡ Guarantee extended to consuming end-user accounts only.

Level 23-1, Premier Suite, One Mont Kiara,
No 1, Jalan Kiara, Mont Kiara
50480 Kuala Lumpur, Malaysia

TEST REPORT

Report No.: D171017607_1

Sample description: Nitrile Glove

Style / Article no. :H2R-35
Test(s) requested :PHYSICAL AND CHEMICAL TEST
Service :REGULAR

APPLICANT: **KIMBERLY-CLARK CORPORATION**
351 Phelps Dr, Irving, TX 75038

Date of receipt : 18 March, 2017
Testing period : 10 March, 2017
: 17 March, 2017

Product category :GLOVE
Product type :NITRILE GLOVE
Test stage :COMPLETE TEST
Supplier name :KIMBERLY-CLARK CORPORATION
Exported to :WORLD WIDE

1. Conclusion:

EN 420/EN 388/EN 374

	Tests description	Conformity
1	4.1. Abrasion resistance	Pass
2	4.1. Cut resistance	Pass
3	4.1. Puncture resistance	Pass
4	4.1. Tear strength resistance	Pass
5	4.3.2. pH - Textile (KCl solution)	Pass
6	5.1.2. Sizing	None
7	5.2. Dexterity	Pass
8	5.2.1. Air Leak Test	Pass
9	5.2.1. Water Leak Test	Pass
10	Azo dyes - Textile	Pass
11	Dimethylfumarate	Pass
12	Polycyclic Aromatic Hydrocarbons	Pass
13	XRF screening	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

International Certification Registrar International Certification Registrar International Certification Registrar

TestLabs

TEST CERTIFICATION OF KIMBERLY-CLARK NITRILE GLOVES

Report No.: D171017607_1

CE

Name and address of certificate owner: **Kimberly-Clark Corporation.**
351 Phelps Dr, Irving, TX 75038

Name and address of manufacturer: **Kimberly-Clark Corporation.**
351 Phelps Dr, Irving, TX 75038

Product name: **Kimberly-Clark Nitrile Glove**

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by TestLabs Malaysia.

No. of test reports: HX2003094478

Certificate issue date: 18.03.2017

Expiration date: 17.03.2021

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8591.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

ICR

Director: Rafał Kalinowski
TESTLABS
Level 23-1, Premier Suite, One Mont Kiara,
No 1, Jalan Kiara, Mont Kiara
50480 Kuala Lumpur

International Certification Registrar International Certification Registrar International Certification Registrar

TestLabs

TEST CERTIFICATION OF KIMBERLY-CLARK NITRILE GLOVES

Report No.: D171017607_1

CE

Name and address of certificate owner: **Kimberly-Clark Corporation.**
351 Phelps Dr, Irving, TX 75038

Name and address of manufacturer: **Kimberly-Clark Corporation.**
351 Phelps Dr, Irving, TX 75038

Product name: **Kimberly-Clark Nitrile Glove**

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

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This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

ICR

Director: Rafał Kalinowski
TESTLABS
Level 23-1, Premier Suite, One Mont Kiara,
No 1, Jalan Kiara, Mont Kiara
50480 Kuala Lumpur

K113423

MAR - 9 2012

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.

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.

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,

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

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 F. Claxton-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)

Elizabeth A. Claverie-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-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. Chavis-Wilson

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

510(k) Number: K113423

April 10, 2020

Kimberly-Clark Corporation
% Wava Truscott
Consultant
Truscott MedSci Associates, LLC
180 Burkemeade Ct
Roswell, Georgia 30075

Re: K200072
Trade/Device Name: KIMTECH Purple Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, the Opioid Fentanyl Citrate, Simulated Gastric acid, and Fentanyl in Simulated Gastric acid
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: January 15, 2020
Received: January 16, 2020

Dear Wava Truscott:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause

for CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200072

Device Name
KIMTECH™ Purple Nitrile™ Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

Indications for Use *(Describe)*
The Nitrile Powder Free patient examination glove is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Test Results Follow:

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time
Blenoxane	(15mg/mL),(15,000 ppm)	>240
Busulfan	(6mg/mL),(6,000 ppm)	>240
Carmustine (BiCNU)	(3.3mg/mL),(3,300 ppm)	>3.6
Cisplatin	(lmg/mL),(1,000 ppm)	>240
Cyclophosphamide/cytoxan	(20mg/mL),(20,000 ppm)	>240
Cytarabine	(100mg/mL),(100,000 ppm)	>240
Dacarbazine(DTIC)	(10mg/mL),(10,000 ppm)	>240
Daunorubicin	(5mg/mL),(5,000 ppm)	>240
Docetaxel	(10mg/mL),(l 0,000ppm)	>240
Doxorubicin	(2mg/mL),(2,000 ppm)	>240
Ellence	(2mg/mL),(2,000 ppm)	>240
Etoposide/Toposar	(20mg/mL,(20,000 ppm)	>240
Fludarabine	(25mg/mL),(25,000 ppm)	>240
Fluorouracil	(50mg/mL),(50,000 ppm)	>240
Gemcitabine	(38mg/mL),(38,000 ppm)	>240
Idarubicin	(1mg/mL),(1,000 ppm)	>240
Ifosfamide	(50mg/mL),(50,000 ppm)	>240
Irinotecan	(20mg/mL),(20,000 ppm)	>240
Mechlorethamine HCL	(l mg/mL),(1,000 ppm)	>240
Melphalan	(5mg/mL),(5,000 ppm)	>240
Methotrexate	(25mg/mL),(25,000 ppm)	>240
Mitomycin C	(0.5mg/mL),(500 ppm)	>240
Mitoxantrone	(2mg/mL),(2,000 ppm)	>240
Paclitaxel	(6mg/mL),(6,000 ppm)	>240
Paraplatin	(10mg/mL),(10,000 ppm)	>240
Rituximab	(10mg/mL),(10,000 ppm)	>240
Thiotepa	(10mg/mL),(10,000 ppm)	>15.9
Trisenox	(0.l mg/mL),(100 ppm)	>240
Vincristine Sulfate	(l mg/ m),(1,000 ppm)	>240

The Fentanyl Citrate and Gastric acid tested as follows:

Fentanyl Citrate	100mcg/2mL	>240
Gastric Acid (simulated)	0.2% NaCl in 0.7% HCL	>240
Fentanyl in Gastric Acid	50/50 Mix	>240

Note: Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively
Warning: Do Not Use With: Carmustine, Thiotepa

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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The information contained herein is being provided in accordance with the requirements of 21 CFR 807.92(c).

510(k) Number: K200072

510(k) Summary Preparation Date: April 6, 2020

KIMTECH™ Purple Nitrile™ Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

1. Submitter:

Company Name:	Kimberly-Clark Corporation
Address:	1400 Holcomb Bridge Road Roswell, GA 30076
Country:	United States of America
Phone:	+1 770 587 8000
Contact Person:	Juan M. Marquez Director, Regulatory Affairs Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30076
Phone	+1 678-352-6069
Fax	+1920-969-4863
E-mail:	Juan.M.Marquez@kcc.com

2. Correspondent:

Company Name:	Wava Truscott, PhD.
Address:	Truscott MedSci Associates, LLC 180 Burkemeade Ct. Roswell, GA 30075
Phone:	+1 (678) 860-1550
Fax:	+1 (770) 552-2887
Email:	Wava.Truscott@gmail.com

3. Device information:

Device Trade Name:	KIMTECH™ Purple Nitrile™ Powder free Examination Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid, and Fentanyl in Simulated Gastric Acid
Classification Name:	Patient Examination Glove
Classification:	Class I (general controls)
Regulation Number:	21 CFR 880-6250
Common name:	Powder-free Nitrile Exam Glove for use with Chemotherapy drugs and Fentanyl
Product Code:	LZC, LZA, QDO

4. **Predicate Device**:
K170686: Brightway Non-Powdered Nitrile Examination Glove Tested for use with Chemotherapy gloves: LZA, LZC (Subject Glove is exactly the same glove, but seeking the additional QDO claim)

K182241: Non-Sterile Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy gloves: LZA, LZC, QDO

5. **Description of the Device**:
KIMTECH™ Purple Nitrile™ Examination Gloves, Powder Free, Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric acid and Fentanyl in Simulated Gastric acid are single use only, non-sterile, disposable gloves. The powder-free gloves are made of a synthetic copolymer of acrylonitrile and butadiene with a purple color additive. The gloves are available in extra small, small, medium, large, and extra-large sizes.

6. **Indications for Use:**

The Nitrile Powder Free patient examination glove is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Test Results Follow:

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time
Blenoxane	(15mg/mL),(15,000 ppm)	>240
Busulfan	(6mg/mL),(6,000 ppm)	>240
Carmustine(BiCNU)	(3.3mg/mL),(3,300 ppm)	>3.6
Cisplatin	(lmg/mL),(1,000 ppm)	>240
Cyclophosphamide/cytoxan	(20mg/mL),(20,000 ppm)	>240
Cytarabine	(100mg/mL),(100,000 ppm)	>240
Dacarbazine(DTIC)	(10mg/mL),(10,000 ppm)	>240
Daunorubicin	(5mg/mL),(5,000 ppm)	>240
Docetaxel	(10mg/mL),(l 0,000ppm)	>240
Doxorubicin	(2mg/mL),(2,000 ppm)	>240
Ellence	(2mg/mL),(2,000 ppm)	>240
Etoposide/Toposar	(20mg/mL,(20,000 ppm)	>240
Fludarabine	(25mg/mL),(25,000 ppm)	>240
Fluorouracil	(50mg/mL),(50,000 ppm)	>240
Gemcitabine	(38mg/mL),(38,000 ppm)	>240
Idarubicin	(1mg/mL),(1,000 ppm)	>240
Ifosfamide	(50mg/mL),(50,000 ppm)	>240
Irinotecan	(20mg/mL),(20,000 ppm)	>240
Mechlorethamine HCL	(l mg/mL),(1,000 ppm)	>240
Melphalan	(5mg/mL),(5,000 ppm)	>240
Methotrexate	(25mg/mL),(25,000 ppm)	>240
Mitomycin C	(0.5mg/mL),(500 ppm)	>240
Mitoxantrone	(2mg/mL),(2,000 ppm)	>240
Paclitaxel	(6mg/mL),(6,000 ppm)	>240
Paraplatin	(10mg/mL),(10,000 ppm)	>240
Rituximab	(10mg/mL),(10,000 ppm)	>240
Thiotepa	(10mg/mL),(10,000 ppm)	>15.9
Trisenox	(0.l mg/mL),(100 ppm)	>240
Vincristine Sulfate	(l mg/ m),(1,000 ppm)	>240
Fentanyl Opioid and Gastric acid tested as follows:		
Fentanyl Citrate	100mcg/2mL	>240
Gastric Acid (simulated)	0.2% NaCl in 0.7% HCL	>240

Fentanyl in Gastric Acid 50/50 Mix >240

Note: Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively

Warning: Do Not Use With: Carmustine, Thiotepa

7. Predicate & Subject Technological Characteristics Comparison Table

Attributes	Standard Where Test Sets Limits	a) Predicate Device: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
Common Name of Device Type	NA	Examination Glove	Examination Glove	Examination Glove	a) Same b) Same
Base Material	NA	Nitrile	Nitrile	Nitrile	c) Same d) Same
Color	NA	Black	Purple	Purple	a) Different than K182241; but, biocompatibility, & physical attributes, show difference in color has not altered glove safety or performance b) Identical to K170686
Glove formulation	NA	Owners own proprietary formula	KC Purple Nitrile 9.5 Chemo Formulation	KC Purple Nitrile 9.5 Chemo Formulation	a) Different than K182241, actual formula unknown b) Identical to K170686
Product Codes	NA	LZA, LZC, QDO	LZA, LZC	LZA, LZC, QDO	a) Same b) Similar-no QDO
Sterile vs Non-Sterile	NA	Non-Sterile	Non-Sterile	Non-Sterile	a) Same b) Same
Prescription or OTC	NA	OTC	OTC	OTC	a) Same b) Same

Attributes	Standard Where Limits Test Limits Set	a) Predicate Device: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
Single Use-Disposable	NA	Yes	Yes	Yes	a) Same b) Same
Intended Use	NA	The device 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.	The device 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.	The device 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.	a) Same b) Same
Indications for use (summary)	NA	In addition to routine examination glove's intended use, the Subject Glove was Tested for use with chemotherapy drugs and the opioid Fentanyl SEE Below for specifics	In addition to routine examination glove's intended use, the Subject Glove was Tested for use with Chemotherapy drugs SEE Below for specifics	KIMTECH™ Purple Nitrile™ Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, the Fentanyl Citrate, Gastric acid, and Fentanyl in Gastric acid SEE Below for specifics	a) Similar: Both tested with Chemotherapy drugs, but some drugs different. Both also tested for Fentanyl, but Subject glove also tested with gastric acid and Fentanyl in gastric acid b) similar: Because they are same glove, same Chemo drugs test breakthrough times identical to K170686; because same test data, but subject glove also tested for Fentanyl citrate, gastric acid, and Fentanyl in gastric acid to be cleared for QDO claims

Attributes	Standard Tests Where Limits Set	a) Predicate Device: K182241 Chemotherapy drugs tested:	b) Predicate Device: K170686 Chemotherapy drugs tested:	Subject Device Glove Chemotherapy drugs tested:	How Does Subject Glove Compare to Predicates
Indications for Use Claims	ASTM D6978 -05 Re - approved 2013	• Carmustine (BCN U) • Cisplatin, • Cyclophosphamide (Cytoxan), • Dacarbazine (DTIC) • Doxorubicin Hydrochloride, • Etoposide (Toposar) • Fluorouracil, • Methotrexate • Paclitazel (Taxol), • Thiotepa • Vincristine Sulfate **Note** Carmustine (BCN U) and Thiotepa have low permeation times In Addition: • Fentanyl	• Blenoxane • Busulfan • Carmustine • Cisplatin • Cyclophosphamide /Cytoxan • Cytarabine • Dacarbazine • Daunorubicin • Docetaxel • Doxorubicin • Ellence • Etoposide/ Toposar • Fluorouracil • Gemcitabine • Idarubicin • Ifosfamide • Mechlorethamine HCL • Melphalan • Methotrexate • Mitomycin C • Mitoxantrone • Paclitaxel • Paraplatin • Rituxmab • Thiotepa • Trisenox • Vincristine Sulfate All >240min except ThioTEPA; Ca1mustine	• Blenoxane • Busulfan • Carmustine • Cisplatin • Cyclophosphamide /Cytoxan • Cytarabine • Dacrabazine • Daunorubicin • Docetaxel • Doxorubicin • Ellence • Etoposide/ Toposar • Fluorouracil • Gemcitabine • Idarubicin • Ifosfamide • Mechlorethamine HCL • Melphalan • Methotrexate • Mitomycin C • Mitoxantrone • Paclitaxel • Paraplatin • Rituximab • Thiotepa • Trisenox • Vincristine Sulfate All >240min except ThioTEPA; Carmustine • Fentanyl Citrate • Gastric acid • Fentanyl Citrate in Gastric acid	a) Similar: both tested CHEMO Drugs for pem1eation, but Subject glove tested more. Both tested Fentanyl, but Subject glove also tested Gastricacid b) Similar: The subject glove has listed the same 29 Chemotherapy dugs as (b) because same glove and the data from Kl70686 used for Subject glove data submission, but the glove has now also be e n tested with additional Fentanyl and Gastric Acid to acquire the QDO code.

Attributes	Standard Where Limits Test Limits Set	a) Predicate Device: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
Caution/ Warning Statements	NA	**Note** Carmustine (BCNU) and Thiotepa have low permeation times	**Note:** Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively. **WARNING: Not for use with: Carmustine, Thiotepa**	**Note:** Carmustine and Thiotepa have extremely low permeation times of 3.6 and 15.9 minutes respectively. **WARNING: Not for Use With: Carmustine, Thiotepa**	a) Similar: Predicate K182241 does not list the breakthrough times in the "Note," nor does it instruct wearer not to use with Carmustine, Thiotepa. Subject Glove is more informative b) Same
Dimensions: Overall length	ASTM D6319 Minimum: 230mm	All sizes comply with length dimensions	All sizes comply with length dimensions	All sizes comply with length dimensions	Same
Dimensions: Width (mean)	ASTM D6319 Minimum: 70 ± 10mm	All sizes comply with length dimensions	All sizes comply with length dimensions	All sizes comply with length dimensions	Same
Dimensions: Palm & Finger Thickness	ASTM D6319 Min.Palm: 0.05mm Finger: 0.05mm	All sizes comply with length dimensions	All sizes comply with length dimensions	All sizes comply with length dimensions	Same
Tensile strength: Before & After Aging	ASTM D6319 Min Before: 14MPa After: 14Mpa	Complies both before and after accelerated aging	Complies both before and after accelerated aging	Complies both before and after accelerated aging	Same

Attributes	Standard Where Limits Test Limits Set	a) Predicate Dev ice: K182241	b) Predicate Device: K170686	Subject Device Glove	How Does Subject Glove Compare to Predicates
Ultimate elongation Before & After aging	**ASTM** D6319 Minimum: Before: 500% After: 400%	Complies both before and after accelerated aging	Complies both before and after accelerated aging	Complies both before and after accelerated aging	Same
Freedom from holes:	**ASTM** D6319 G1, AQL 2.5 7 Accept 8 Reject	Pass	Pass	Pass	Same
Powder-Free	**ASTM** D6319 Maximum <2mg/ glove	Less than 2.0mg per glove; Pass	Less than 2.0mg per glove; Pass	Less than 2.0mg per glove; Pass	Same
Biocompatibility	ISO 10993- 11 Systemic Toxicity Test	Under conditions of the study, t he device extracts did not elicit a systemic response in the model animal.	Under conditions of the study, the device extracts did not elicit a systemic response in the model animal.	Under conditions of the study, the device extracts did not elicit a systemic response in the model animal.	Same
	ISO 10993-10 Primary **Skin** Irritation on Rabbits	Under Condit ions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Under Condit ions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Under Condit ions of this study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Same
	ISO 10993-10 Magnusson & Kligman Guinea pig Maximization	Under Condit ions of this study, the polar and non- polar device extracts were found not to be sensitizers to the animal model.	Under Conditions of this study, the polar and non-polar device extracts were found not to be sensitizers to the animal model.	Under Conditions of this study, the polar and non- polar device extracts were found not to be sensitizers to the animal model.	Same

8. **Summary of Non-Clinical Performance Tests:**

Non-Clinical Testing was conducted to demonstrate that the proposed device met all required design specifications. The test results demonstrated that the proposed device met the performance criteria as specified utilizing the following test methods, standards, and specifications:

ASTM D6319-10 Standard D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application

ASTM D412-2006a (Reapproved 2013) Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension

ASTM D573-2004 (Reapproved 2010) Standard Test Method for Rubber-Deterioration in an Air Oven

ASTM D3767-03 Standard Practice for Rubber Measurement of Dimensions

ASTM D5151-2006 (Reapproved 2015) Standard Test Method for Detection of holes in Medical Gloves

ASTM D6124-2006 (Reapproved 2015) Standard Tested Method for Residual Powder on Medical Gloves

ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes

ISO 10993-10 Biological Evaluation of medical Devices-Part 10: Tests for Irritation and Sensitization

ISO 10993-11 Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity

9. **Conclusion:**

The conclusions drawn is that the physical attributes and the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as, or better than, the legally marketed predicate devices.

HISTORY

Since 1988, we have specialized in the development, manufacturing, and distribution of protective infection control solutions.

At Cranberry, we stress utmost importance on providing products of superior quality. Therefore, we constantly strive to develop products with the highest protection, comfort, and strength. After thriving in this industry for so many years, we truly understand your needs and demands as a professional. Be assured that our dynamic team is always moving forward, researching, and seeking to provide you with only the best.

We have established successful partnerships in many countries. Even so, we are excited to expand our networks and distribution further so that Cranberry gloves are made available in every country.

As a professional, you are passionate about the health and comfort of your clients. At Cranberry, we are passionate about yours.

FIRST TOUCH

In an average manufacturing process, gloves and masks may come in human skin contact up to 8 times. With ultimate hygiene in mind, Cranberry products are First Touch® manufactured, examined, and packaged with zero direct skin contact exposure. Don't just put on any gloves and masks, look for our First Touch® logo and be assured that you are doing the best you can to protect yourself and your patients.

CERTIFICATIONS

Quality Managment Systems

ISO 13485 & ISO 9001

Test Report No. 7191
dated 23 Mar 2018

PSB Singapore

Choose certainty.
Add value.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by
o., Ltd. on 25 Jan 2018 and 09 Mar 2018.

TESTED FOR:

, Shandong,
China.

TEST DATE:

26 Jan 2018 to 06 Feb 2018 and 22 Mar 2018

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	Blue	BS0002	12150511	XS	100	Ltd.
				03060511		69	
				12150521	S	100	
				12080311	M	100	
				12090411	L	100	
				12070611	XL	407	

Lot size as specified by client: 200,000 pieces

METHOD OF TEST:

1. EN 455-1:2000 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
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www.tuv-sud-psb.sg
Co. Reg. : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

RESULTS:

Sample: Powder Free Nitrile Examination Gloves, BS0002

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	1	Passed
		S		10	315	1	Passed
		M		10	315	2	Passed
		L		10	315	6	Passed
		XL		10	315	4	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	XS	≥ 240	13	250	Passed
		S		13	250	Passed
		M		13	255	Passed
		L		13	250	Passed
		XL		13	248	Passed
	b) Width (mm)	XS	≤ 80	13	73	Passed
		S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	106	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	6.4	Passed
		S		13	8.6	Passed
		M		13	6.1	Passed
		L		13	6.1	Passed
		XL		13	6.6	Passed
	b) Force at break after challenge testing (N)	XS	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed
		S		13	9.0	Passed
		M		13	7.3	Passed
		L		13	6.6	Passed
		XL		13	7.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Powder Free Nitrile Examination Gloves, BS0002

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks		Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is powder-free glove, based on client's declaration letter version 2018001		NA
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients		NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'		NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	XS	0.61 mg per glove	Passed
			S	0.63 mg per glove	Passed
			M	0.97 mg per glove	Passed
			L	0.86 mg per glove	Passed
			XL	0.48 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove		NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

REMARKS:

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 22 Mar 2018.
2. For size XS, results for EN 455-2:2015 Clause 4 Dimensions is based on lot no. 03060511, while the rest of the results are based on lot no. 12150511.
3. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2018003.
4. NA: Not applicable for the submitted sample.

Shareen Chan
Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo : Powder Free Nitrile Examination Gloves, BS0002

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

Blue Sail Medical Co Ltd
Qilu Chemical Industrial Park
No 21 Qingtian Road
Zibo
Shandong
China

This is to certify that the following products tested under SATRA reports referenced:CHM0291439/1944/JH & STE0289547 have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11521-01/E00-00	BS01020X	Disposable medical Nitrile examination glove	EN ISO 374-1:016

Dated: 14th November 2019

This certificate is valid until: November 2020

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

510(k) Premarket Notification

New Search | Back To Search Results

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K983334
Device Name	NITRILE POWDER FREE EXAMINATION GLOVES
Applicant	CRANBERRY (M) SDN. BHD. LOT 85, JALAN PORTLAND, TASEK INDUSTRIAL ESTATE Ipoh Perak, MY 31400
Applicant Contact	Chong Yoon Tat
Correspondent	CRANBERRY (M) SDN. BHD. LOT 85, JALAN PORTLAND, TASEK INDUSTRIAL ESTATE Ipoh Perak, MY 31400
Correspondent Contact	Chong Yoon Tat
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	09/23/1998
Decision Date	02/19/1999
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Page Last Updated: 06/29/2020

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Mr.**********
Director
Cranberry (M) Sdn. Bhd.
****
****
****
MALAYSIA

Re: K983334
Trade Name: Nitrile Powder-Free Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: January 15, 1999
Received: January 19, 1999

Dear Mr. **********

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CRANBERRY (M) SDN. BHD. (104994 - W)
(A MEMBER OF THE YEE LEE GROUP)

Applicant : CRANBERRY (M) SDN. BHD.
****
****
****

510(k) Number (if known): K*83*3*

Device Name: Nitrile Powder Free Examination Glove - Cranberry

Indications For Use:

This product is a patient examination glove. It 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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) N K98****

Prescription Use_____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109)