



Food and Drug Administration
10903 New Hampshire Avenue
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April 21, 2017

Brightway Holdings Sdn Bhd.
G. Baskaran
Group Managing Director
Lot 1559, Jalan Istimewa,
Batu Belah
Klang, Selangor, 42100 MY

Re: K162294

Trade/Device Name: BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12",
POWDER FREE, [PURPLE] TESTED FOR USE WITH
CHEMOTHERAPY DRUGS

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA, LZC

Dated: March 11, 2017

Received: March 15, 2017

Dear G. Baskaran:

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 contact the Division of Industry and Consumer Education 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>. 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

<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 Industry and Consumer Education 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,

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162294

Device Name

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS

Indications for Use (Describe)

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS is a disposable device intended for medical purpose, to be worn on the examiners hand or finger to prevent contamination between patient and examiner.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Test Chemotherapy Drug Name and Concentration	Minimum Breakthrough Detection Time
• Arsenic Trioxide (0.1mg/ml),(100ppm)	>240 Minutes
• Bleomycin Sulfate (15mg/ml),(15,000 ppm)	>240 Minutes
• Busulfan(6mg/ml),(6,000 ppm)	>240 Minutes
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	127.5 Minutes
• Cisplatin(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Cyclophosphamide/Cytosan(20mg/ml), (20,000 ppm)	>240 Minutes
• Cytarabine(100mg/ml), (100,000 ppm)	>240 Minutes
• Dacarbazine(DTIC) 10mg/ml, (10,000 ppm)	>240 Minutes
• Daunorubicin(5mg/ml), (5,000 ppm)	>240 Minutes
• Docetaxel(10mg/ml), (10,000 ppm)	>240 Minutes
• Doxorubicin HCL(2mg/ml),(2,000 ppm)	>240 Minutes
• Ellence (2mg/ml), (2,000 ppm)	>240 Minutes
• Etoposide /Toposar (20mg/ml), (20,000 ppm)	>240 Minutes
• Fludarabine (25mg/ml), (25,000 ppm)	>240 Minutes
• Fluorouracil(50mg/ml), (50,000 ppm)	>240 Minutes
• Gemcitabine/Gemzar (38mg/ml), (38,000 ppm)	>240 Minutes
• Idarubicin(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Ifosfamide (50mg/ml), (50,000 ppm)	>240 Minutes
• Irinotecan(20mg/ml), (20,000 ppm)	>240 Minutes
• Mechlorethamine HCl(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Melphalan(5mg/ml), (5,000 ppm)	>240 Minutes
• Methotrexate(25mg/ml),(25,000 ppm)	>240 Minutes
• Mitomycin C(0.5 mg/ml), (500 ppm)	>240 Minutes
• Mitoxantrone(2mg/ml),(2,000 ppm)	>240 Minutes
• Paclitaxel(6.0mg/ml),(6,000 ppm)	>240 Minutes
• Paraplatin (10mg/ml),(10,000 ppm)	>240 Minutes
• Rituximab(10mg/ml),(10,000 ppm)	>240 Minutes
• Thiotepa (10mg/ml),(10,000 ppm)	>240 Minutes
• Trisenox(0.1mg/ml), (100 ppm)	>240 Minutes
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240 Minutes

Please note that the following drug noted permeation times below 240 mins: Carmustine (BCNU) 127.50 mins.

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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510(K) SUMMARY

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [PURPLE]
TESTED FOR USE WITH CHEMOTHERAPY DRUGS

1. **Submitter :**

Company Name : **BRIGHTWAY HOLDINGS SDN. BHD.**

Street Address : Lot 1559, Jalan Istimewa,
Batu Belah, 42100 Klang
Selangor Darul Ehsan.

Country : Malaysia

Phone No. : 603-3343 1007 & 603-3343 1094.

Fax No. : 603-3341 4800

E-mail Address : brightway@brightway919.com

Contact Person : Mr. G. Baskaran (Group Managing Director)
baskar@brightway919.com
Mr. Felix Darrel (Group Marketing Manager)
felix.marketing@brightway919.com

2. **Preparation Date :** 12th April 2017

3. **Name of the Device :**

Device trade or proprietary name: K162294 - BRIGHTWAY BRAND NITRILE
EXAMINATION GLOVES 12", POWDER FREE, [PURPLE] TESTED FOR USE WITH
CHEMOTHERAPY DRUGS

Device Classification Name: Polymer Patient Examination Glove

(21 CFR 880.6250)

Device common or usual name: NITRILE EXAMINATION GLOVE TESTED FOR USE WITH
CHEMOTHERAPY DRUGS

FDA Device Class : Class 1

Product Code : LZC , LZA

4. Identification of the Device :

Class I patient Examination Nitrile gloves, Powder Free, LZA, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.

Predicate Device:

Legally Marketed Devices to which Substantial Equivalence is claimed:

K113423: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12")
Tested for Use with Chemotherapy Drugs

5. Device Description :

The subject device in this 510(k) Notification is a Purple Nitrile Examination gloves, tested for use with Chemotherapy drugs.

The subject device is a patient examination glove made from nitrile compound, Purple in color, powder free and non sterile (as per 21 CFR 880.6250, class I).

The principle operation of the medical device to provide single use barrier protection for the wearer and the device meets all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

This device also complies with requirements for Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy drugs as per ASTM D6978-05

6. Intended use of the Device

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS is a disposable device intended for medical purpose, to be worn on the examiners hand or finger to prevent contamination between patient and examiner.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Test Chemotherapy Drug Name and Concentration	Minimum Breakthrough Detection Time
• Arsenic Trioxide (0.1mg/ml),(100ppm)	>240 Minutes
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• Busulfan(6mg/ml),(6,000 ppm)	>240 Minutes
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	127.5 Minutes
• Cisplatin(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Cyclophosphamide/Cytoxan(20mg/ml), (20,000 ppm)	>240 Minutes
• Cytarabine(100mg/ml), (100,000 ppm)	>240 Minutes
• Dacarbazine(DTIC) 10mg/ml, (10,000 ppm)	>240 Minutes
• Daunorubicin(5mg/ml), (5,000 ppm)	>240 Minutes
• Docetaxel(10mg/ml), (10,000 ppm)	>240 Minutes
• Doxorubicin HCL(2mg/ml),(2,000 ppm)	>240 Minutes
• Ellence (2mg/ml), (2,000 ppm)	>240 Minutes
• Etoposide /Toposar (20mg/ml), (20,000 ppm)	>240 Minutes
• Fludarabine (25mg/ml), (25,000 ppm)	>240 Minutes
• Fluorouracil(50mg/ml), (50,000 ppm)	>240 Minutes
• Gemcitabine/Gemzar (38mg/ml), (38,000 ppm)	>240 Minutes
• Idarubicin(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Ifosfamide (50mg/ml), (50,000 ppm)	>240 Minutes
• Irinotecan(20mg/ml), (20,000 ppm)	>240 Minutes
• Mechlorethamine HCl(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Melfalan(5mg/ml), (5,000 ppm)	>240 Minutes
• Methotrexate(25mg/ml),(25,000 ppm)	>240 Minutes
• Mitomycin C(0.5 mg/ml), (500 ppm)	>240 Minutes
• Mitoxantrone(2mg/ml),(2,000 ppm)	>240 Minutes
• Paclitaxel(6.0mg/ml),(6,000 ppm)	>240 Minutes
• Paraplatin (10mg/ml),(10,000 ppm)	>240 Minutes
• Rituximab(10mg/ml),(10,000 ppm)	>240 Minutes
• Thiotepa (10mg/ml),(10,000 ppm)	>240 Minutes
• Trisenox(0.1mg/ml), (100 ppm)	>240 Minutes
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240 Minutes

Please note that the following drug noted permeation times below 240 mins: Carmustine (BCNU) 127.50 mins.

7. Substantial Equivalence Based on Assessment of Non-Clinical Performance Data

Testing was performed per ASTM D6319-10 , ASTM D5151-06, ASTM D6124- 06,ISO 10993-10:2010. The glove meet standards requirement referenced in section 6.0 above.

Biocompatibility tests indicated that under the conditions of the studies, the gloves were non-sensitizing, non-irritating, and does not induce an acute systemic toxicity.

8. Summary of Technical Characteristics and Substantial Equivalence Compared to Predicate Device :

The predicate device in scope is as follows:

K113423: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12")
Tested for Use with Chemotherapy Drugs

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE,
[PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS is substantially equivalent
in safety and effectiveness to K113423: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-
Free Exam Gloves (12") Tested for Use with Chemotherapy Drugs

The subject device and predicate device use a similar Nitrile barrier film to achieve a device for the intended use. The properties between the subject device and the predicate device are compared in the following table:

Device Performance						
Characteristics	Standard	K113423: Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves - 9.5" Length	K113423: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves - 12" Length	Predicate Device K113423: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12") Tested for Use with Chemotherapy Drugs <i>PREDICATE DEVICE MAIN COMPARISON</i>	Subject Device : BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS <i>SUBJECT DEVICE MAIN COMPRISON</i>	Result of Comparison
Labeling	N/A	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	Same
Device Materials	N/A	Nitrile Compound	Nitrile Compound	Nitrile Compound	Nitrile Compound	Same
Colour	N/A	Purple	Purple	Purple	Purple	Same

Device Tolerances and Specifications & Performance Data						
Tensile strength : Before and after ageing	ASTM 6319-10	> 14 Mpa	> 14 Mpa	> 14 Mpa	> 14 Mpa	Same
Ultimate Elongation: Before and after ageing	ASTM 6319-10	> 500 %	> 500 %	> 500 %	> 500 %	Same
Freedom from Pinholes	ASTM 6319-10 (FDA 1000 ml water leak test)	Pass	Pass	Pass	Pass	Same
Dimensions						
Length	ASTM 6319-10	> 235 mm	> 295 mm	> 295 mm	> 295 mm (295 mm minimum -325 mm)	Same
Width	ASTM 6319-10	70±10 mm to 120±10 mm (sizes XS to XL)	70±10 mm to 120±10 mm (sizes XS to XL)	70±10 mm to 120±10 mm (sizes XS to XL)	70±10 mm to 120±10 mm (sizes XS to XL)	Same
Thickness	ASTM 6319-10	> 0.05 mm (Palm 0.12mm Finger : 0.15mm)	> 0.05 mm (Palm 0.12mm Finger : 0.15mm)	> 0.05 mm (Palm 0.12mm Finger : 0.15mm)	> 0.05 mm (Palm :0.14mm- 0.18mm Finger : 0.20mm- 0.24mm)	Same
Residual Powder :	ASTM D6124	Less than 2 mg per glove ; PASS	Less than 2 mg per glove ; PASS	Less than 2 mg per glove ; PASS	Less than 2 mg per glove ; PASS	Same

Biocompatibility						
Primary Skin Irritation test	ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Same
Dermal sensitization assay	ISO 10993-10	Under conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer	Same
Acute Systemic Toxicity	ISO 10993-11	Under conditions of the study, the device does not induce acute systemic toxicity	Under conditions of the study, the device does not induce acute systemic toxicity	Under conditions of the study, the device does not induce acute systemic toxicity	Under conditions of the study, the device does not induce acute systemic toxicity	Same
Chemotherapy Testing ASTM D6978-05						
Test CHEMOTHERAPY Drug Name	Drug Concentration	Minimum Breakthrough Detection Time (minutes)				
Arsenic Trioxide	0.1mg/ml	N/A	N/A	-	> 240	Predicate not tested, Subject Device tested and showed no breakthrough after 240mins
Bleomycin Sulfate	15mg/ml	N/A	N/A	> 240	> 240	Same
Busulfan	6mg/ml	N/A	N/A	> 240	> 240	Same

Carmustine BCNU	3.3mg/ml	N/A	N/A	30.7	> 127.5	Predicated Device breakthrough at 30.7 Minutes. Subject device noted permeation times below 240 mins: Carmustine (BCNU) 127.50 mins.
Cisplatin	1.0mg/ml	N/A	N/A	> 240	> 240	Same
Cyclophosphamide/ Cytosan	20mg/ml	N/A	N/A	> 240	> 240	Same
Cytarabine	100mg/ml	N/A	N/A	> 240	> 240	Same
Dacarbazine (DTIC)	10mg/ml,	N/A	N/A	> 240	> 240	Same
Daunorubicin	5mg/ml	N/A	N/A	> 240	> 240	Same
Docetaxel	10mg/ml	N/A	N/A	> 240	> 240	Same
Doxorubicin HCL	2mg/ml	N/A	N/A	> 240	> 240	Same
Ellence	2mg/ml	N/A	N/A	> 240	> 240	Same
Etoposide /Toposar	20mg/ml	N/A	N/A	> 240	> 240	Same
Fludarabine	25mg/ml	N/A	N/A	> 240	> 240	Same
Fluorouracil	50mg/ml	N/A	N/A	> 240	> 240	Same
Gemcitabine/ Gemzar	38mg/ml	N/A	N/A	> 240	> 240	Same
Idarubicin	1.0mg/ml	N/A	N/A	> 240	> 240	Same
Ifosfamide	50mg/ml	N/A	N/A	> 240	> 240	Same
Irinotecan	20mg/ml	N/A	N/A	> 240	> 240	Same
Mechlorethamine HCl	1.0mg/ml	N/A	N/A	> 240	> 240	Same
Melphalan	5mg/ml	N/A	N/A	> 240	> 240	Same
Methotrexate	25mg/ml	N/A	N/A	> 240	> 240	Same
Mitomycin C	0.5 mg/ml	N/A	N/A	> 240	> 240	Same

Mitoxantrone	2mg/ml	N/A	N/A	> 240	> 240	Same
Paclitaxel	6.0mg/ml	N/A	N/A	> 240	> 240	Same
Paraplatin (Carboplatin)	10mg/ml	N/A	N/A	> 240	> 240	Same
Rituximab	10mg/ml	N/A	N/A	> 240	> 240	Same
Thiotepa	10mg/ml	N/A	N/A	> 240	> 240	Same
Trisenox	0.1mg/ml	N/A	N/A	> 240	> 240	Same
Vincristine Sulfate	1.0mg/ml	N/A	N/A	> 240	> 240	Same
Warning Statement	ASTM D6978-05	N/A	N/A	Please note that the following drug has low permeation times of less than 60 minutes: Carmustine (BCNU) 30.7 mins.	Please note that the following drug noted permeation times below 240 mins: Carmustine (BCNU) 127.50 mins.	Same

12.0 Conclusion

Based on intended uses, technological characteristics and Non-Clinical performance data, the subject device; BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS is substantially equivalent to the predicate device K113423: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12") Tested for Use with Chemotherapy Drugs

The subject device meets the requirements of ASTM D 6319- 10 standards as well as applicable 21 CFR references, and meets FDA recognized standards for physical properties requirements, pinhole requirements, biocompatibility requirements which are as shown and discussed above.

Based on the complete list of non-clinical tests, the subject device herein mentioned, is as safe, as effective, and performs as well as the legally marketed predicate device.