DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2016

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

Re: K161215
Trade/Device Name: Brightway Brand Nitrile Examination Gloves, Powder Free, [Sterling/Grey] Tested For Use With Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: November 16, 2016
Received: November 21, 2016

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 yours,

Michael J. Ryan -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161215

Device Name
BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [STERLING/GREY]
TESTED FOR USE WITH CHEMOTHERAPHY DRUGS

Indications for Use *(Describe)*
BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [STERLING/GREY] TESTED FOR USE WITH CHEMOTHERAPHY DRUGS is a disposable device intended for medical purpose worn on the examiner's 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
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	5.4 Minutes
• Cisplatin(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Cyclophosphamide/Cytoxan(20mg/ml), (20,000 ppm)	>240 Minutes
• Dacarbazine(DTIC) 10mg/ml, (10,000 ppm)	>240 Minutes
• Doxorubicin HCL(2mg/ml),(2,000 ppm)	>240 Minutes
• Etoposide /Toposar (20mg/ml), (20,000 ppm)	>240 Minutes
• Fluorouracil(50mg/ml), (50,000 ppm)	>240 Minutes
• Ifosfamide (50mg/ml), (50,000 ppm)	>240 Minutes
• Mitoxantrone(2mg/ml),(2,000 ppm)	>240 Minutes
• Paclitaxel/Taxol(6.0mg/ml),(6,000 ppm)	>240 Minutes
• Thiotepa (10mg/ml),(10,000 ppm)	40.4 Minutes
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240 Minutes

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) 5.4 minutes and Thiotepa 40.4 minutes.

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

K161215

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [STERLING/GREY] TESTED FOR USE WITH CHEMOTHERAPHY 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 :** 30th November 2016

3. **Name of the Device :**

Device trade or proprietary name: BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [STERLING/GREY] TESTED FOR USE WITH CHEMOTHERAPHY DRUGS

Device Classification Name: Polymer Patient Examination Glove
(21 CFR 88.6250)

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

FDA Device Class: Class 1

Product Code: LZA, LZC

4. Identification of the Device :

Class I patient Examination glove and tested for use with Chemotherapy Drugs, Powder Free, LZC, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.

5. Device Description:

The subject device in this 510(k) Notification is a Sterling/Grey Nitrile Examination gloves, with claims and tested for use with Chemotherapy drugs.

The subject device is a patient examination glove made from nitrile compound, Sterling or Grey 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 is manufactured in facilities compliant to ISO 9001:2008 certified in Manufacture of Non Sterile Natural (Latex) and Synthetic Latex (Nitrile) Examination, Surgical and Industrial Gloves & Nitrile Sheath

The device is manufactured to comply with ISO 13485:2003 / EN ISO 13485:2012 Manufacture of Non Sterile Natural (Latex) and Synthetic Latex (Nitrile) Examination & Sterile Surgical Gloves

6. Intended use of the Device

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [STERLING/GREY] TESTED FOR USE WITH CHEMOTHERAPHY DRUGS is a disposable device intended for medical purpose worn on the examiner's 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
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	5.4 Minutes
• Cisplatin(1.0mg/ml), (1,000 ppm)	>240 Minutes
• Cyclophosphamide/Cytoxan(20mg/ml), (20,000 ppm)	>240 Minutes
• Dacarbazine(DTIC) 10mg/ml, (10,000 ppm)	>240 Minutes
• Doxorubicin HCL(2mg/ml),(2,000 ppm)	>240 Minutes
• Etoposide /Toposar (20mg/ml), (20,000 ppm)	>240 Minutes
• Fluorouracil(50mg/ml), (50,000 ppm)	>240 Minutes
• Ifosfamide (50mg/ml), (50,000 ppm)	>240 Minutes
• Mitoxantrone(2mg/ml),(2,000 ppm)	>240 Minutes
• Paclitaxel/Taxol(6.0mg/ml),(6,000 ppm)	>240 Minutes
• Thiotepa (10mg/ml),(10,000 ppm)	40.4 Minutes
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240 Minutes

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) 5.4 minutes and Thiotepa 40.4 minutes.

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 and 16 CFR Part 1500.41.

Biocompatibility tests indicated that under the conditions of the studies, the gloves were non-sensitizing, non-irritating, and non-systemically toxic

8. Legally Marketed Device to which Substantial Equivalence is Claimed

The legally marketed predicate device in scope is as follows:

1) K151750 - Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile

Substantial Equivalence Comparison Table:

The subject Device, K161215 - BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPHY CLAIM is substantially equivalent in safety and effectiveness to K151750 - Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile

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:

Characteristics	Subject Device K161215	Predicate Device K151750	Comments
	Sterling/Grey	Blue, White	
Manufacturer	Brightway Holdings Sdn Bhd	Kossan International Sdn Bhd	N/A
510(K) Number	K161215	K151750	N/A
Identification	Nitrile Examination Gloves, Powder Free,Sterling/Grey Coloured, Tested For Use with Chemotherapy Drugs	1. Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs 2. Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs	N/A
Device Classification Name/ Regulation Number	Patient Examination Glove/ 21 CFR Part 880.6250	Patient Examination Glove/ 21 CFR Part 880.6250	Same
Product Code	LZA, LZC	LZA, LZC	Same

Intended Use	BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [STERLING/GREY] TESTED FOR USE WITH CHEMOTHERAPHY DRUGS is a disposable device intended for medical purpose worn on the examiner's hand or finger to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	Same
Materials	Nitrile	Nitrile	Same
Color	Grey / Sterling	Blue, and White	The difference in color does not raise any safety issues
Design	Meet Requirements of ASTM D6319	Extra Small Small Medium Large Extra Large Double Extra Large	Same
Single Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Length	minimum 230 mm, target 242 mm, maximum 258 mm, Meets Requirements of ASTM D6319	min 230 mm / ≥ 230mm, Meets Requirements of ASTM D6319	Same
Thickness(mm)	[redacted]		
Cuff	0.05-0.07	0.032-0.050	Meets requirements of ASTM D6319 Subject Device

Palm	0.06-0.09	0.055-0.085	Meets requirements of ASTM D6319
Finger	0.07-0.10	0.065-0.095	Meets requirements of ASTM D6319
Powder Free Residue	≤ 2mg/glove	≤ 2mg/glove	Same
Physical Properties	Meets Requirements of ASTM D6319	Meets Requirements of ASTM D6319	Same
Freedom from pinholes testing	Tested in accordance with ASTM D5151 test method. Pass quality level at G2 AQL 1.0	Tested in accordance with ASTM D5151 test method. Pass quality level at G1 AQL 1.5	Tested to Same standard. Subject device tested to a more stringent criteria of G2 AQL 1.0
Biocompatibility Test			
Dermal Sensitization (as ISO 10993- 10:2010)	Not a contact sensitizer under the conditions of the study	Not a contact sensitizer under the conditions of the study	Same
Primary Skin Irritation Test (as ISO 10993-10:2010)	Not a primary skin irritant under the conditions of the study	Not a primary skin irritant under the conditions of the study	Same

Systemic Toxicity (ISO 10993-11)	Under the conditions of the study, no mortality or no evidence of Systemic Toxicity was observed	N/A	Predicate device was not tested for Systemic Toxicity, Subject device was tested for Acute Systemic Toxicity and no mortality or evidence of Systemic Toxicity was observed
Labelling Features	- Non-sterile - Powder Free - Examination Gloves - Ambidextrous, by Size - Single Use Only - Device Color - Manufactured Date : - Lot Number: - Quantity by Weight - Made in Malaysia	- Non-sterile - Powder Free - Examination Gloves - Ambidextrous, by Size - Single Use Only - Device Color - Manufactured for: - Lot Number: - Quantity by Weight - Made in Malaysia	Same
Chemotherapy Drugs Permeation Test			
Chemotherapy Drugs (Concentrations)	Minimum Breakthrough Detection Time in Minutes	Minimum Breakthrough Detection Time in Minutes	
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	5.4	10.1	Below 30 minutes permeation time, same as the predicate device
• Cisplatin(1.0mg/ml), (1,000 ppm)	>240	>240	Same
• Cyclophosphamide/Cytoxan(20mg/ml), (20,000 ppm)	>240	>240	Same
• Dacarbazine(DTIC) 10mg/ml, (10,000 ppm)	>240	>240	Same
• Doxorubicin HCL(2mg/ml),(2,000 ppm)	>240	>240	Same
• Etoposide /Toposar (20mg/ml), (20,000 ppm)	>240	>240	Same

• Fluorouracil(50mg/ml), (50,000 ppm)	>240	>240	Same
• Ifosfamide (50mg/ml), (50,000 ppm)	>240	>240	Same
• Mitoxantrone(2mg/ml),(2,000 ppm	>240	>240	Same
• Paclitaxel/Taxol(6.0mg/ml),(6,000 ppm)	>240	>240	Same
• Thiotepa (10mg/ml),(10,000 ppm)	40.4	30.2(Blue) and 10.4(White)	Predicate device (Blue) at 30.2 minutes; and (White) below 30 minutes Subject Device had a permeation time of 40.4 mins which exceeded 30 mins. less than 60 mins.
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240	>240	Same
Warning Statement	WARNING: Not for use with Carmustine, ThioTEPA	WARNING: Do Not Use with Carmustine and Thiotepa	Same
Labelling Claim	Tested for Use with Chemotherapy Drugs	Tested for Use with Chemotherapy Drugs	Same

11.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the subject device is substantially equivalent to the predicate device K151750 - Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile

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

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