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

March 31, 2017

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

Re: K162186
Trade/Device Name: BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: February 8, 2017
Received: February 23, 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,

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)*
K162186

Device Name
BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM

Indications for Use *(Describe)*
BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM 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 product has been tested with chemotherapy drugs in accordance with ASTM D6978. The breakthrough detection times are as follows:

Test Chemotherapy Drug Name and Concentration	Minimum Breakthrough Detection Time
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	4.3 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(6.0mg/ml),(6,000 ppm)	>240 Minutes
• Thiotepa (10mg/ml),(10,000 ppm)	10.9 Minutes
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240 Minutes

Please note that Carmustine and Thiotepa have extremely low permeation times of 4.3 minutes and 10.9 minutes, respectively.

Warning: Do not use with Carmustine and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM

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 :** 13th March 2017

3. **Name of the Device :**

Device trade or proprietary name: BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM

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 glove tested for use with Chemotherapy Drugs, Powder Free, LZA and LZC, 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:

K081089 - Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-EXTRA Powder-Free Exam Gloves with Chemotherapy Drug Use Claim

5. **Device Description :**

The subject device in this 510(k) Notification is Sterling/Grey coloured 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 colour, 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, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM 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 product has been tested with chemotherapy drugs in accordance with ASTM D6978. The breakthrough detection times are as follows:

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Please note that Carmustine and Thiotepa have extremely low permeation times of 4.3 minutes and 10.9 minutes, respectively.

Warning: Do not use with Carmustine and Thiotepa.

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. 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 non-systemically toxic

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

The predicate device in scope is as follows

1. K081089 - Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-EXTRA Powder-Free Exam Gloves with Chemotherapy Drug Use Claim

The subject device; BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM is substantially equivalent in safety and effectiveness to K081089 - Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-EXTRA Powder-Free Exam Gloves with Chemotherapy Drug Use Claim

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**	**Predicate Device : K 081089 - Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-EXTRA Powder-Free Exam Gloves with Chemotherapy Drug Use Claim**	**Subject Device : BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM**	**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.	Same
Device Materials	N/A	Nitrile Compound	Nitrile Compound	Same
Colour	N/A	Sterling	Sterling / Grey	Same

Device Tolerances and Specifications & Performance Data				
Tensile strength : Before and after ageing	ASTM 6319-10	> 14 Mpa	> 14 Mpa	Same
Ultimate Elongation : Before and after ageing	ASTM 6319-10	> 500 %	> 500 %	Same
Freedom from Pinholes :	ASTM 6319-10 (FDA 1000 ml water leak test)	Pass	Pass	Same
Dimensions: Length	ASTM 6319-10	> 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)	Same
Thickness	ASTM 6319-10	> 0.05 mm (palm & finger)	> 0.05 mm (Palm :0.075mm-0.08mm Finger : 0.085mm-0.10mm)	Same
Residual Powder :	ASTM 6319-10,	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	Same
Dermal sensitization assay	ISO 10993-10	Under conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer	Same
Systemic Toxicity	ISO 10993-11	Pass	Pass	Same

Chemical Permeation / Chemotherapy Testing				
Resistance to Permeation	ASTM D6978-05	Carmustine and Thiotepa have extremely low permeation times of less than 30 minutes	Carmustine and Thiotepa have extremely low permeation times of less than 30 minutes	Same

9. Conclusion

Based on intended use, technological characteristics and Non-Clinical performance data, the subject device; BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES 12", POWDER FREE, [STERLING/GREY] WITH CHEMOTHERAPY CLAIM is substantially equivalent to the predicate device K081089 - Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-EXTRA Powder-Free Exam Gloves with Chemotherapy Drug Use Claim.

Based on intended uses, technological characteristics and non-clinical performance data, the subject device is substantially equivalent to the predicate device K081089 - Kimberly-Clark STERLING* Nitrile & STERLING* NITRILE-EXTRA Powder-Free Exam Gloves with Chemotherapy Drug Use Claim.

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 devices.