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

July 14, 2017

Brightway Holdings Sdn. Bhd.
% Dr. Wava Truscott
Consultant
Truscott Medsci Associates, LLC
180 Burkemeade Ct
Roswell, Georgia 30075

Re: K170686
Trade/Device Name: Nitrile Examination Gloves, Powder Free (Purple) 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: June 25, 2017
Received: June 26, 2017

Dear Dr. 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. 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,

Tara A. Ryan -S

for

Lori Wiggins
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)*

K170686

Device Name

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

Indications for Use *(Describe)*

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE [PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS is a disposable device intended for medical purpose 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
• Blenoxane (15mg/ml),(15,000 ppm)	>240 Minutes
• Busulfan(6mg/ml),(6,000 ppm)	>240 Minutes
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	3.6 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 (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 HCI(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)	15.9 Minutes
• Trisenox(0.1mg/ml), (100 ppm)	>240 Minutes
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240 Minutes

Please note that Carmustine and Thiotepa have extremely low permeation times of 3,6 minutes 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)

510(K) SUMMARY

K170686

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, 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 :** July 13, 2017

3. **Name of the Device :**

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

Device Classification Name: Polymer Patient Examination Glove (21 CFR 88-.6250)

Device common or usual name: Powder-Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs

FDA Device Class : Class 1

Product Code : LZC, LZA

4. **Identification of the Device :**

This Class 1 medical device; product code LZA, LZC with the Trade Name: BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE (Purple) TESTED FOR USE WITH CHEMOTHERAPY DRUGS, was tested for Chemotherapy drug penetration resistance per ASTM D6978-05 and meets all the requirements of ASTM D6319-10 and FDA 21 CFR 880.6250.

Predicate device:

Legally marked device to which substantial equivalence is claimed:

1) K992162 - Safeskin Purple Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim

5. **Device Description :**

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

The subject device is a patient examination glove made from nitrile compound, Purple 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 / Indication of Use**

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

This device has been tested with chemotherapy drugs and their breakthrough detection times are as follows:

Test Chemotherapy Drug Name and Concentration	Minimum Breakthrough Detection Time
• Blenoxane (15mg/ml),(15,000 ppm)	>240 Minutes
• Busulfan(6mg/ml),(6,000 ppm)	>240 Minutes
• Carmustine (BCNU) (3.3mg/ml),(3,300 ppm)	3.6 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 (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)	15.9 Minutes
• Trisenox(0.1mg/ml), (100 ppm)	>240 Minutes
• Vincristine Sulfate(1.0mg/ml),(1,000 ppm)	>240 Minutes

Please Note: Carmustine and ThioTEPA have extremely low permeation times with breakthrough detected in less than 30 minutes: Carmustine (3.3mg/mL): 3.6 minutes; ThioTEPA (10mg/mL): 15.9 minutes

WARNING: Not for Use with: Carmustine, ThioTEPA

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

a.) Testing was performed per ASTM D6319: Standard Specification for Nitrile Examination Gloves for Medical Application, utilizing the currently re-approved versions of the test methods there-in referenced:

- ASTM D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D573 Test Method for Rubber—Deterioration in an Air Oven
- ASTM D3578 Specification for Rubber Examination Gloves
- ASTM D3767 Practice for Rubber—Measurement of Dimensions
- ASTM D5151 Test Method for Detection of Holes in Medical Gloves
- ASTM D6124 Test Method for Residual Powder on Medical Gloves
- ISO 2859 Sampling Procedures and Tables for Inspection by Attributes

Test results show that under the conditions of the testing, there is no difference in physical attributes between the proposed device and the predicate device.

b.) Both the proposed device and the predicate were tested for use with chemotherapy drugs per:

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

c.) Biocompatibility testing was performed utilizing:

- ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for Irritation and Sensitization. Both dermal irritation and sensitization (Magnusson & Kingman) were performed.
- ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for Systemic toxicity were conducted as had been performed on the predicate device.

Both the proposed device and the predicate device demonstrated that they were non-irritating and non-sensitizing, and that they did not demonstrate systemic toxicity under conditions of the studies performed.

All testing performed demonstrated that under the conditions of the test or study conducted, that the proposed medical device and the predicate device performed the same or similarly.

8. **A summary, side by side Comparison Table is presented:**

510(k) Summary Table

Comparison of Proposed Device to Predicate Device (pg. 1 of 2)

Device Characteristics	Test Standard	Proposed Device	Predicate Device K992162	Comparison Analysis
Trade Name	N/A	Brightway Brand Nitrile Examination Gloves, Powder Free, [Purple] Tested for Use with Chemotherapy Drugs	Safeskin Purple Powder-Free Nitrile Examination Gloves Tested for use with Chemotherapy Drugs	Similar
510(k) Reference	N/A		K992162	N/A
Common Name	N/A	Patient Examination Glove	Patient Examination Glove	Same
Product Code	N/A	LZA, LZC	LZA, LZC	Same
Intended use	N/A	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by chemotherapy Drugs.	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by chemotherapy Drugs.	Same
Labeling	N/A	There are no special labeling claims. Does not claim hypoallergenic on label	There are no special labeling claims. Does not claim hypoallergenic on label	Same
Regulation Number	N/A	21 CFR 880.6250	21 CFR 880.6250	Same
Materials	N/A	Nitrile	Nitrile	Same
Color	N/A	Purple	Purple	Same
Textures fingers	N/A	Yes	Yes	Same
Design Configurations	ASTM D6319-10	Extra-Small Small Medium Large Extra-Large	Extra-Small Small Medium Large Extra-Large	Same
Dimensions Length	ASTM D6319-10	All sizes comply with length dimensions	All sizes comply with length dimensions	Same
Dimensions Width	ASTM D6319-10	All sizes comply with width dimensions	All sizes comply with width dimensions	Same
Dimensions Thickness	ASTM D6319-10	All sizes comply with thickness dimensions	All sizes comply with thickness dimensions	Same

Part 10. Executive Summary

Comparison of Proposed Device to Predicate Device (pg. 2 of 2)

Device Characteristics	Test Standard	Proposed Device	Predicate Device K992162	Comparison Analysis
Physical Properties - Tensile Strength	ASTM D6319-10	Complies with ASTM D6319-10 both before and after accelerated aging	Complies with ASTM D6319-10 both before and after accelerated aging	Same
Physical Properties - Elongation	ASTM D6319-10	Complies with ASTM D6319-10 both before and after accelerated aging	Complies with ASTM D6319-10 both before and after accelerated aging	Same
Freedom from Holes	ASTM D6319-10 by D5151-06	Pass	Pass	Same
Powder Free Designation	ASTM D6319-10 by D6124-06	Less than 2.0 mg per glove; Pass	Less than 2.0 mg per glove; Pass	Same
Biocompatibility	ISO 10993-10:2010 Reapproved 2014	Under conditions of the test, Not a skin irritant	Under conditions of the test Not a skin irritant	Same
	ISO 10993-10:2010 Reapproved 2014	Under conditions of the test, Not a skin sensitizer	Under conditions of the test, Not a skin sensitizer	Same
	ISO 10993-11:2006 Reapproved 2010	Under conditions of the test Does not cause systemic toxicity	Under conditions of the test Does not cause systemic toxicity	Same
Prescription vs. OTC	N/A	OTC	OTC	Same
Sterile vs. Non-sterile	N/A	Non-Sterile	Non-Sterile	Same
Single Use	N/A	Yes	Yes	Same
Tested for use with Chemotherapy Drugs	ASTM D6978-05	**Please note:** Carmustine and ThioTEPA have extremely low breakthrough times of less than 30 minutes	**Please note:** Carmustine and ThioTEPA have extremely low breakthrough times of less than 30 minutes	Same
Warning	**N/A**	**WARNING: Not for Use with: Carmustine, ThioTEPA**	**WARNING: Not for Use with: Carmustine, ThioTEPA**	Same

9.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the subject device BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [PURPLE] TESTED FOR USE WITH CHEMOTHERAPY DRUGS is substantially equivalent to the predicate device K992162 - Safeskin Purple Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim.

The subject device meets the requirements of ASTM D 6319- 10 standards as well as applicable 21 CFR and meets FDA recognized, physical properties requirements, pinhole requirements, powder free requirements, resistance to permeation by chemotherapy drugs testing, biocompatibility studies and labeling requirements presented in this document.

There are no safety or efficacy issues or new claims different from the "substantially equivalent" predicate.

Based on the complete list of non-clinical tests, biological safety studies, labeling, intended use, materials, and processes of manufacture, the subject device herein proposed is as safe, as effective, and performs as well as the legally marketed predicate device.