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

January 5, 2017

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

Re: K162146
Trade/Device Name: Brightway Brand Nitrile Examination Gloves, Powder Free (Lavender)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: July 19, 2016
Received: August 1, 2016

Dear Dr. 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)*
K162146

Device Name
BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [LAVENDER]

Indications for Use *(Describe)*
BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [LAVENDER] is a disposable device intended for medical purpose, to be worn on the examiners hand or finger to prevent contamination between patient and examiner.

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, POWDER FREE, [LAVENDER]

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 :** 4th January 2017

3. **Name of the Device :**

Device trade or proprietary name: BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [LAVENDER]

Device Classification Name: Patient Examination Glove

(21 CFR 880.6250)

Device common or usual name: NITRILE EXAMINATION GLOVE

FDA Device Class : Class 1

Product Code : 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:

1) K081260 - KIMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves

5. **Device Description :**

The subject device in this 510(k) Notification is a Lavender Examination Glove.

The subject device is a patient examination glove made from a Nitrile compound, Lavender 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 that 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, [LAVENDER] is a disposable device intended for medical purpose, to be worn on the examiners hand or finger to prevent contamination between patient and examiner.

7. Specification For Nitrile gloves

7.1. Dimension and Thickness of Gloves

Dimension Measurement & Water Tight Test Report

Certificate No : 6G11 01 **Date : 11/07/2016**

Brand : Lavender Nitrile Exam Glove.

Prd Description : Brightway Brand Nitrile Examination Gloves, Powder Free [Lavender]

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

Dimension Measurement

Test Method: ASTM D6319-10
Sample tested: 20 pieces per Batch.
Random Sampling based on ISO2859-1:1999; S2 AQL 2.5, Ac=1 Rej=2

Batch No: 6G02 01

Sample No.	Size	Weight (g)	Length (mm)	Width (mm)	Thickness (mm)		
					Finger Tip	Palm	Cuff
1	XS	2.8	243	78	0.095	0.065	0.055
2	XS	2.7	240	77	0.090	0.070	0.055
3	XS	2.8	243	78	0.090	0.075	0.06
4	XS	2.9	242	77	0.095	0.065	0.055
5	S	3.1	243	84	0.090	0.070	0.055
6	S	3.0	241	85	0.095	0.070	0.06
7	S	3.0	242	83	0.090	0.075	0.055
8	S	2.9	243	84	0.095	0.065	0.06
9	M	3.1	241	97	0.095	0.065	0.065
10	M	3.3	242	98	0.10	0.070	0.06
11	M	3.2	242	97	0.095	0.070	0.055
12	M	3.1	243	98	0.095	0.075	0.06
13	L	3.9	243	114	0.090	0.065	0.065
14	L	3.8	241	112	0.10	0.070	0.055
15	L	3.7	242	112	0.095	0.075	0.06
16	L	3.8	243	113	0.095	0.070	0.055
17	XL	4.1	242	121	0.090	0.065	0.055
18	XL	4.0	241	120	0.090	0.070	0.06
19	XL	4.0	242	121	0.095	0.075	0.06
20	XL	4.1	243	120	0.090	0.070	0.06
Specification For XS		*2.7 ± 0.3g*	*Min - 230 Tar – 240 Max - 258*	*Min - 60 Tar – 70 Max - 80*	*Min - 0.06 Tar – 0.08 Max – 0.11*	*Min - 0.05 Tar – 0.07 Max – 0.09*	*Min - 0.04 Tar – 0.06 Max – 0.08*
Specification For Small		*2.9 ± 0.3g*	*Min - 230 Tar – 240 Max - 258*	*Min - 70 Tar – 80 Max - 90.*	*Min - 0.06 Tar – 0.08 Max – 0.11*	*Min - 0.05 Tar – 0.07 Max – 0.09*	*Min - 0.04 Tar – 0.06 Max – 0.08*
Specification For Medium		*3.2 ± 0.3g*	*Min - 230 Tar – 240 Max - 258*	*Min - 85 Tar – 95 Max - 105*	*Min - 0.06 Tar – 0.08 Max – 0.11*	*Min - 0.05 Tar – 0.07 Max – 0.09*	*Min - 0.04 Tar – 0.06 Max – 0.08*
Specification For Large		*3.8 ± 0.3g*	*Min - 230 Tar – 240 Max - 258*	*Min - 100 Tar – 110 Max - 120*	*Min - 0.06 Tar – 0.08 Max – 0.11*	*Min - 0.05 Tar – 0.07 Max – 0.09*	*Min - 0.04 Tar – 0.06 Max – 0.08*
Specification For XL		*4.0 ± 0.3g*	*Min - 230 Tar – 240 Max - 258*	*Min - 110 Tar – 120 Max - 130*	*Min - 0.06 Tar – 0.08 Max – 0.11*	*Min - 0.05 Tar – 0.07 Max – 0.09*	*Min - 0.04 Tar – 0.06 Max – 0.08*
Number of non-conformance			*0*	*0*	*0*	*0*	*0*
Status			*Pass*	*Pass*	*Pass*	*Pass*	*Pass*

7.2. Gloves Physical Properties and Freedom From Holes

Water-tight Test

Test method: ASTM D5151
Sample tested: 200 pieces per Batch.
Random Sampling based on ISO2859-1:1999; G2 AQL 1.5, Ac=7 Rej=8

Location of holes	Size : X - Small	Size : Small	Size : Medium	Size : Large	Size : X - Large
Cuff	0	0	1	0	0
Palm	2	0	0	0	0
Finger-tip	0	0	0	0	0
Total defective Found	**1**				
Acceptance number	**7**				
Status	**Pass**				

BRIGHTWAY HOLDINGS SDN BHD
Testing Services
Physical Properties Analysis Report

Certificate No : 6G11 25 **Date : 11/07/2016**
Customer : N/A
Brand : LAVENDER NITRILE EXAM GLOVES
PO No : N/A
PI No : N/A
Batch No : 6G02 01
Product Description : Brightway Brand Nitrile Examination Gloves, Powder Free [Lavender]
Sample Receiving Date : : 03.07.2016
Sampling Plan : Single Normal S2 AQL: 2.5 Acc/Rej : 1/2 .
Sizes Comprising Of : XS, S, M, L & XL
Test Method : ASTM D 6319 - 10
Test Conducted on : 10/07/2016
Aging : 70 +/- 2 deg C for 168 Hrs .

Test Environment Condition		Room Temperature (^{0}C) : 23 RH (%) : 48			Room Temperature (^{0}C) : 23 RH (%) : 48	
		Before Aging			After Aging	
Sample No	Size	Modulus At 500% (MPa)	Tensile Strength (MPa)	Ultimate Elongation (%)	Tensile Strength (MPa)	Ultimate Elongation (%)
1	XS	18.9	26.125	592.6	27.412	510.6
2	XS	19.5	27.986	561.7	26.322	529.4
3	XS	17.9	29.632	578.8	25.879	492.5
4	XS	18.2	26.231	592.3	27.653	503.7
5	S	19.5	27.588	581.6	26.968	536.9
6	S	17.4	29.451	559.2	25.121	511.6
7	S	18.3	28.212	563.5	27.454	507.8
8	S	19.2	26.102	586.4	26.958	498.8
9	M	18.9	27.877	577.3	25.525	522.9
10	M	17.7	29.636	591.6	24.118	537.7
11	M	19.2	26.096	554.2	25.412	542.3
12	M	18.9	27.741	596.8	26.589	519.2
13	L	17.5	26.655	583.7	26.470	507.3
14	L	18.6	28.825	573.1	27.965	544.9
15	L	19.4	29.821	565.8	25.231	520.5
16	L	17.6	26.644	680.4	26.598	518.1
17	XL	18.2	27.132	593.2	27.415	502.6
18	XL	19.5	29.990	570.8	24.626	533.8
19	XL	19.2	26.512	588.9	26.118	510.7
20	XL	18.4	27.849	591.6	25.956	546.4
Average Result		18.6	27.805	588.8	26.075	523.5
Cust. Requirement		N/A	16 (Min)	500 (Min)	15(Min)	450 (Min)

Gloves meet all the specification listed in ASTM D 6319-10

8. 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

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

The predicate device in scope is as follows

1) K081260 - KlMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [LAVENDER] is substantially equivalent in safety and effectiveness to K081260 - KlMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves

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 : K081260 - Kimberly Clark* Lavender* Nitrile Powder Free Examination Glove**	**Subject Device : K162146 - BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [LAVENDER]**	**Result of Comparison**
Labeling	N/A	There are no special labeling claims and do not claim gloves as hypoallergenic on labels. No shelf life claim.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels. No shelf life claim.	Same
Device Materials	N/A	Nitrile Compound	Nitrile Compound	Same

Colour	N/A	Lavender	Lavender	Same
Device Tolerances and Specifications & Performance Data				
Tensile strength : **before and after ageing**	ASTM 6319-10	Meets requirements	Meets requirements	Same
Ultimate Elongation : **Before and after ageing**	ASTM 6319-10	Meets requirements	Meets requirements	Same
Freedom from Pinholes	ASTM 6319-10	Meets requirements	Meets requirements	Same
Dimensions:	ASTM 6319-10	Meets requirements	Meets requirements	Same
Residual Powder :	ASTM 6319-10, ASTM D6124	Meets requirements	Meets requirements	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 contact sensitizer	Under conditions of the study, not a contact sensitizer	Same
Systemic Toxicity	ISO 10993-11	Non-systemically toxic	Non-systemically toxic	Same

12.0 Conclusion

Based on intended uses, technological characteristics and Non-Clinical performance data, the subject device; BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [LAVENDER] is substantially equivalent to the predicate device K081260 - KlMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves.

Based on intended uses, technological characteristics and non-clinical performance data, the subject device is substantially equivalent to the predicate device K081260 - KlMBERLY-CLARK* LAVENDER* NITRILE Powder-Free Exam Gloves

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.

There are no safety/efficacy issues or new claims from the ''substantial equivalence comparison'' between the products cited.

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.