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 24, 2017

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

Re: K163267
Trade/Device Name: Brightway Nitrile Examination Glove, powder free (blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: November 7, 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,

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)*
K163267

Device Name
BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE (BLUE)

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

K163267

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [BLUE]

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 :** 18th March 2017

3. **Name of the Device :**

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

Device Classification Name: Polymer Patient Examination Glove

(21 CFR 88.6250)

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 ;
K143477- Nitrile Patient Examination Gloves, Powderfree, Blue Color

5. **Device Description :**

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

The subject device is a patient examination glove made from a Nitrile compound, Blue 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, [BLUE] 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

**Certificate No : 6H22 06** **Date : 22/08/2016**

**Brand : 9.5" Textured Non Sterile Blue Nitrile Exam Gloves.**

**Prd Description : Brightway Brand Textured Non Sterile Nitrile Examination Gloves, Powder Free (Blue)**

**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: 6H10 03**

| Sample No. | Size | Weight (g) | Length (mm) | Width (mm) | Thickness (mm) | | |
|---|---|---|---|---|---|---|---|
| | | | | | Finger Tip | Palm | Cuff |
| 1 | XS | 4.5 | 240 | 75 | 0.16 | 0.13 | 0.085 |
| 2 | XS | 4.6 | 241 | 76 | 0.155 | 0.125 | 0.09 |
| 3 | XS | 4.6 | 241 | 76 | 0.16 | 0.13 | 0.085 |
| 4 | XS | 4.5 | 240 | 78 | 0.165 | 0.12 | 0.095 |
| 5 | S | 5.3 | 242 | 87 | 0.155 | 0.125 | 0.085 |
| 6 | S | 5.2 | 239 | 87 | 0.155 | 0.13 | 0.09 |
| 7 | S | 5.4 | 242 | 87 | 0.165 | 0.13 | 0.085 |
| 8 | S | 5.3 | 242 | 86 | 0.155 | 0.125 | 0.095 |
| 9 | M | 6.0 | 240 | 97 | 0.16 | 0.13 | 0.085 |
| 10 | M | 6.1 | 239 | 96 | 0.155 | 0.125 | 0.09 |
| 11 | M | 5.9 | 241 | 96 | 0.16 | 0.125 | 0.085 |
| 12 | M | 6.1 | 240 | 97 | 0.165 | 0.13 | 0.095 |
| 13 | L | 7.2 | 240 | 115 | 0.155 | 0.12 | 0.085 |
| 14 | L | 7.1 | 241 | 116 | 0.16 | 0.125 | 0.09 |
| 15 | L | 7.0 | 241 | 117 | 0.165 | 0.13 | 0.08 |
| 16 | L | 7.2 | 240 | 115 | 0.155 | 0.125 | 0.095 |
| 17 | XL | 7.3 | 240 | 122 | 0.165 | 0.125 | 0.085 |
| 18 | XL | 7.4 | 239 | 121 | 0.155 | 0.12 | 0.085 |
| 19 | XL | 7.2 | 242 | 120 | 0.16 | 0.13 | 0.09 |
| 20 | XL | 7.3 | 241 | 122 | 0.155 | 0.12 | 0.095 |
| *Specification For XS* | | *4.6 ± 0.3g* | *Min - 230<br>Tar – 242<br>Max - 258* | *Min - 60<br>Tar – 70<br>Max - 80* | *Min - 0.12<br>Tar – 0.15<br>Max – 0.19* | *Min - 0.08<br>Tar – 0.12<br>Max – 0.16* | *Min - 0.06<br>Tar – 0.09<br>Max – 0.13* |
| *Specification For Small* | | *5.2 ± 0.3g* | *Min - 230<br>Tar – 242<br>Max - 258* | *Min - 70<br>Tar – 80<br>Max - 90.* | *Min - 0.12<br>Tar – 0.15<br>Max – 0.19* | *Min - 0.08<br>Tar – 0.12<br>Max – 0.16* | *Min - 0.06<br>Tar – 0.09<br>Max – 0.13* |
| *Specification For Medium* | | *6.1 ± 0.3g* | *Min - 230<br>Tar – 242<br>Max - 258* | *Min - 85<br>Tar – 95<br>Max - 105* | *Min - 0.12<br>Tar – 0.15<br>Max – 0.19* | *Min - 0.08<br>Tar – 0.12<br>Max – 0.16* | *Min - 0.06<br>Tar – 0.09<br>Max – 0.13* |
| *Specification For Large* | | *7.0 ± 0.3g* | *Min - 230<br>Tar – 242<br>Max - 258* | *Min - 100<br>Tar – 110<br>Max - 120* | *Min - 0.12<br>Tar – 0.15<br>Max – 0.19* | *Min - 0.08<br>Tar – 0.12<br>Max – 0.16* | *Min - 0.06<br>Tar – 0.09<br>Max – 0.13* |
| *Specification For XL* | | *7.2 ± 0.3g* | *Min - 230<br>Tar – 242<br>Max - 258* | *Min - 110<br>Tar – 120<br>Max - 130* | *Min - 0.12<br>Tar – 0.15<br>Max – 0.19* | *Min - 0.08<br>Tar – 0.12<br>Max – 0.16* | *Min - 0.06<br>Tar – 0.09<br>Max – 0.13* |
| *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- 06
Sample tested: 200 pieces per Batch.
Random Sampling based on ISO2859-1:1999; G2 AQL 1.0, Ac=5 Rej=6

| Location of holes | Size : X - Small | Size : Small | Size : Medium | Size : Large | Size : X - Large |
|---|---|---|---|---|---|
| Cuff | 0 | 0 | 0 | 0 | 0 |
| Palm | 0 | 1 | 0 | 0 | 0 |
| Finger-tip | 0 | 0 | 0 | 0 | 0 |
| **Total defective Found** | **1** | | | | |
| **Acceptance number** | **5** | | | | |
| **Status** | **Pass** | | | | |

**BRIGHTWAY HOLDINGS SDN BHD**
**Testing Services**
**Physical Properties Analysis Report**

**Certificate No** : **6H22 168** **Date : 22/08/2016**
**Customer** : **N/A**
**Brand** : **9.5''Textured Non Sterile Blue Nitrile Exam Glove.**
**PO No** : **N/A**
**PI No** : **N/A**
**Batch No** : **6H10 03**
**Product Description** : **Brightway Brand Textured Non Sterile Nitrile Examination Glove, Powder Free [Blue]**
**Sample Receiving Date :** : **14.08.2016**
**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** : **21/08/2016**
**Aging** : **70 +/- 2 deg C for 168 Hrs .**

| Test Environment Condition | | Room Temperature (°C) : 23 RH (%) : 48 | | | Room Temperature (°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 | 16.5 | 23.546 | 575.0 | 21.155 | 495.5 |
| 2 | XS | 18.2 | 24.852 | 546.2 | 22.459 | 481.2 |
| 3 | XS | 17.4 | 24.865 | 537.8 | 21.398 | 477.2 |
| 4 | XS | 19.3 | 23.654 | 562.3 | 23.546 | 499.3 |
| 5 | S | 16.5 | 24.784 | 543.7 | 21.654 | 487.7 |
| 6 | S | 18.4 | 23.123 | 569.5 | 22.478 | 454.0 |
| 7 | S | 17.7 | 23.321 | 544.4 | 21.398 | 451.2 |
| 8 | S | 18.6 | 24.512 | 562.3 | 23.485 | 486.8 |
| 9 | M | 17.4 | 25.845 | 543.7 | 21.145 | 495.6 |
| 10 | M | 19.4 | 24.956 | 569.5 | 22.409 | 485.5 |
| 11 | M | 16.9 | 23.698 | 544.4 | 21.545 | 479.6 |
| 12 | M | 17.6 | 24.654 | 575.4 | 23.348 | 496.5 |
| 13 | L | 18.2 | 25.415 | 568.7 | 21.145 | 492.9 |
| 14 | L | 17.8 | 23.154 | 522.2 | 22.365 | 457.3 |
| 15 | L | 16.3 | 24.856 | 519.4 | 21.398 | 489.3 |
| 16 | L | 18.7 | 23.156 | 530.5 | 23.348 | 487.7 |
| 17 | XL | 18.5 | 25.852 | 517.0 | 21.145 | 496.9 |
| 18 | XL | 17.8 | 23.465 | 596.0 | 22.409 | 498.5 |
| 19 | XL | 16.9 | 25.865 | 543.1 | 21.478 | 488.5 |
| 20 | XL | 17.8 | 23.456 | 541.8 | 23.369 | 489.7 |
| Average Result | | 17.8 | 24.351 | 550.6 | 22.134 | 484.5 |
| Cust. Requirement | | N/A | 14 (Min) | 500 (Min) | 14(Min) | 400 (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 did not reveal any systemic toxicity

## 9. Summary of Technical Characteristics and Substantial Equivalence Comparison Table

The predicate device in scope is as follows:

1) K143477- Nitrile Patient Examination Gloves, Powderfree, Blue Color

BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [BLUE] is substantially equivalent in safety and effectiveness to K143477- Nitrile Patient Examination Gloves, Powderfree, Blue Color.

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: K143477- Nitrile Patient Examination Gloves, Powderfree, Blue Color** | **Subject Device : K161215 - BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [BLUE]** | **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 |

| | | | | |
|---|---|---|---|---|
| **Device Description** | | The subject device is a patient examination glove made of synthetic nitrile latex compound. It is non-sterile, powderfree and is Blue in color. The device is ambidextrous and can be worn on either the left or right hand. The device meets ASTM 06319-10: Standard specification for Nitrile Examination Gloves for Medical Application. The subject device is substantially equivalent to legally marketed Nitrile examination gloves identified as Product code LZA. The device is for over-the counter single use. | The subject device in this 510(k) Notification is a Blue Examination Glove.<br><br>The subject device is a patient examination glove made from a Nitrile compound, Blue in colour, powder free and non sterile (as per 21 CFR 880.6250, class I).<br><br>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.<br><br>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<br><br>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 | |
| **Indications for use** | N/A | The Nitrile Patient Examination gloves, Powderfree, Blue color, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner | BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [BLUE] is a disposable device intended for medical purpose, to be worn on the examiners hand or finger to prevent contamination between patient and examiner. | Same |
| **Color** | N/A | Blue | Blue | Same |
| **Device Tolerances and Specifications & Performance Data** | | | | |
| **Tensile strength :**<br><br>**before and after ageing** | ASTM 6319-10 | > 14Mpa ; PASS | > 14Mpa ; PASS | Same |
| **Ultimate Elongation :** | ASTM 6319-10 | > 500 % ; PASS | > 500 % ; PASS | Same |

| | | | | |
|---|---|---|---|---|
| **Before and after ageing** | | | | |
| **Freedom from Pinholes** | ASTM 6319-10 (FDA 1000 ml water leak test) | Pass | Pass | Same |
| **Dimensions:** | | | | |
| **Length** | ASTM 6319-10 | > 230 mm (240-400mm) | >230 mm (230-258mm) | 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 :0.08mm-0.16mm Finger : 0.12mm-0.19mm) | Same |
| **Residual Powder :** | ASTM 6319-10, ASTM D6124 | 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 | N/A | Under conditions of study, did not reveal any systemic toxicity | Predicated Device did not undertake the testing. Subject Device met requirements under ISO 109930-11 |

## 10.0 Conclusion

Based on intended uses, technological characteristics and Non-Clinical performance data, the subject device; BRIGHTWAY BRAND NITRILE EXAMINATION GLOVES, POWDER FREE, [BLUE] is substantially equivalent to the predicate device K143477- Nitrile Patient Examination Gloves, Powder Free, Blue Color

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.