April 13, 2023

JR Engineering & Medical Technologies (M) SDN. BHD.
% Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE 114
Aurora, Illinois 60504

Re: K222350
Trade/Device Name: Sterile Nitrile Surgical Gloves Powder Free
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: March 13, 2023
Received: March 13, 2023

Dear Manoj Zacharias:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222350

Device Name

Sterile Nitrile Surgical Gloves  Powder Free

Indications for Use *(Describe)*

A Sterile Nitrile Surgical Gloves Powder Free is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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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**510K SUMMARY**

**K222350**

Date of Preparation: April 10, 2023

As required by: 21CFR § 807.92

## A. APPLICANT INFORMATION


| | |
|---|---|
| Submitter Name | JR Engineering & Medical Technologies (M) SDN. BHD |
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| Designation | Managing Director |
| Contact Number | +6012 224 6677 |
| Contact Email | ganeshjrmt@gmail.com |
| US Agent | Manoj Zacharias |
| US Agent Address | Liberty Management Group Ltd.<br>75 Executive Dr. Ste 114 Aurora, IL 60504 USA |
| US Agent Telephone | 1 (630) 270-2921 |
| US Agent Fax | 1 (815) 986-2632 |
| US Agent Email | manoj@libertymanagement.us |


## B. Device Identification

| | |
|---|---|
| Common Name | Surgical Gloves |
| Device Name | Sterile Nitrile Surgical Gloves Powder Free |
| Product Proprietary or Trade Name | **JR MEDIC** |
| Classification Name | Surgeon's Gloves |
| Device Classification | 1 |
| Product Code | KGO |
| Regulation Number | 21 CFR 878.4460 |

## C. Predicate Device

| | |
|---|---|
| 510k Number | K170515 |
| Common Name | Surgical Gloves |
| Device Name | Sterile Nitrile Surgical Gloves, Powder Free |
| Classification name | Surgeon's Gloves |
| Device Classification | 1 |
| Product Code | KGO |
| Regulation Number | 21 CFR 878.4460 |

## D. Description of the Device

The proposed device, Sterile Nitrile Surgical Gloves Powder Free is a sterile and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination.

The proposed device is made of synthetic rubber latex, as per standard ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves.
The classification is: Type II - gloves compounded from synthetic rubber latex.
The proposed device is Sterile Nitrile Surgical Gloves Powder Free, and is produced in sizes 6, 6 ½, 7, 7 ½, 8, 8 ½, and 9. All sizes share the same White color.
The proposed device is sterilized using Gamma Radiation method to achieve the Sterility Assurance Level (SAL) of $10^{-6}$ while packaged to maintain sterility. The shelf life is 3 years.

**E. Technological Characteristics**

| **Characteristic** | **Subject device K222350** | **Predicate device K170515** | **Remarks** |
|---|---|---|---|
| Product Code | KGO | KGO | Same |
| Regulation No. | 21 CFR 878.4460 | 21 CFR 878.4460 | Same |
| Class | 1 | 1 | Same |
| Intended Use | A Sterile Nitrile Surgical Gloves Powder Free is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. | The powder-free nitrile surgical Gloves, is a sterile and single use devise made of synthetic rubber intended to be worn by operation room personnel to protect a surgical wound from contamination. The gloves do not contain lubricating or dusting powder | Similar |
| Powdered or Powder free | Powder free | Powder free | Same |
| Material | Synthetic Rubber | Synthetic Rubber | Same |
| Color | White | White | Same |
| Classification as per ASTMD3577-19, Standard Specification for Rubber Surgical Gloves | Type II - gloves compounded from Synthetic rubber latex | Type II - gloves compounded from Synthetic rubber latex | Same |
| Sterilization | Radiation, SAL- $10^{-6}$ | ETO/as well as Radiation, SAL- $10^{-6}$ | Similar |
| Label and Labeling | Meet FDA's label Requirements | Meet FDA's label Requirements | Same |
| Type of use | Over the counter use | Over the counter use | Same |
| **Dimensions Length**:- Min 265mm | 307mm | 265mm min | Similar |
| **Size: Width**<br>6.0 (76±6mm)<br>6.5 (83±6mm)<br>7.0 (89±6mm)<br>7.5 (95±6mm)<br>8.0 (102±6mm)<br>8.5 (108±6mm)<br>9.0 (114±6mm) | <br>78mm<br>85mm<br>88mm<br>97mm<br>103mm<br>110mm<br>116mm | <br>76±6mm<br>83±6mm<br>89±6mm<br>95±6mm<br>102±6mm<br>108±6mm<br>114±6mm | Similar |
| Cuff, Palm, Finger Tip Thickness<br>Min 0.10mm | Cuff- 0.12mm<br>Palm- 0.18mm<br>Finger Tip- 0.21mm | Cuff, Palm & Finger has a min 0.10mm thickness | Similar |
| Tensile Strength<br>Unaged<br>17MPa minimum | 24.20MPa | 17MPa min | Similar |
| Ultimate Elongation<br>Unaged<br>650% minimum | 871% | 650% min | Similar |

| | | | |
|---|---|---|---|
| Stress at 500%<br>Unaged<br>7.0 MPa Max | 6.1MPa | 7.0MPa max | Similar |
| Tensile Strength<br>Aged<br>12MPa minimum | 18.53MPa | 12 MPa min | Similar |
| Ultimate Elongation<br>Aged<br>490% minimum | 653% | 490% min | Similar |
| Freedom from Holes | AQL 1.5 | AQL 2.5 | Similar |
| Powder residue for powder free glove<br>Powder content<br>< 2 mg/Glove | 0.40mg/Glove | < 2mg/Glove | Similar |
| Skin Irritation | Under conditions of the testing, not an irritant | Under conditions of the testing, not an irritant | Similar |
| Skin Sensitization | Under the conditions of the testing, not a sensitizer | Under the conditions of the testing, not a sensitizer | Similar |
| In vitro cytotoxicity | Under the conditions of the testing, not cytotoxic | Under the conditions of the testing, not cytotoxic | Similar |
| Material Mediated pyrogenicity | Under the conditions of the testing, non-pyrogenic | No data available | Different |
| Bacterial Endotoxin Test | < 20 EU/glove | No data available | Different |
| Systemic Toxicity | Under the conditions of the testing, no acute systemic toxicity | No data available | Different |
| Sterilization Modality | Radiation | Radiation/EtO | Similar |
| Sterility Assurance Level | $10^{-6}$ | $10^{-6}$ | Same |
| Shelf Life | 3 years | Unknown | Different |

**F. Summary of Non-Clinical Performance Testing**

| **Test Method** | **Purpose** | **Acceptance Criteria** | **Result** |
|---|---|---|---|
| ASTM D5151-2019 | Freedom from holes<br>Before aging | AQL 1.5<br>3 non-consecutive lots | Pass |
| ASTM D5151-2019 | Freedom from holes<br>After accelerated aging<br>70±2°C for 166±2 h | AQL 1.5<br>3 non-consecutive lots | Pass |
| ASTM D5151-2019 | Freedom from holes<br>After accelerated aging<br>50±2°C for 90±1 days | AQL 1.5<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Tensile strength<br>Before aging | Minimum 17MPa for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical | Tensile strength<br>After accelerated aging<br>70±2°C for 166±2 h | Minimum 12MPa for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |

| | | | |
|---|---|---|---|
| Gloves | | | |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Tensile strength<br>After accelerated aging<br>50±2°C for 90±1 days | Minimum 12MPa for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Ultimate Elongation<br>Before aging | Minimum 650% for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Ultimate elongation<br>After accelerated aging<br>70±2°C for 166±2h | Minimum 490% for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Ultimate elongation<br>After accelerated aging<br>50±2°C for 90±1 days | Minimum 490% for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Stress at 500% elongation<br>Before accelerated aging | Maximum 7.0MPa for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Stress at 500% elongation<br>After accelerated aging<br>70±2°C for 166±2h | Maximum 7.0MPa for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | Stress at 500% elongation<br>After accelerated aging<br>50±2°C for 90±1 days | Maximum 7.0MPa for all sizes<br>AQL 4%<br>3 non-consecutive lots | Pass |
| ASTM F1929, Test Method for detecting seal leaks in porous medical packaging by dye penetration | Package integrity<br>After accelerated aging<br>70±2°C for 166±2h | No penetration<br>AQL 0.65%<br>3 non-consecutive lots | Pass |
| ASTM F1929, Test Method for detecting seal leaks in porous medical packaging by dye penetration | Package integrity<br>After accelerated aging<br>50±2°C for 90±1 days | No penetration<br>AQL 0.65%<br>3 non-consecutive lots | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical | To determine the length of the gloves | Min 265mm for all sizes | Size 6: Pass<br>Size 6 ½: Pass<br>Size 7: Pass |

| | | | | | |
|---|---|---|---|---|---|
| Gloves | | | | Size 7 ½ | Pass |
| | | | | Size 8 | Pass |
| | | | | Size 8 ½ | Pass |
| | | | | Size 9 | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | To determine the width of the gloves | Size 6 | 76±6mm | Size 6 | Pass |
| | | Size 6 ½ | 83±6mm | Size 6 ½ | Pass |
| | | Size 7 | 89±6mm | Size 7 | Pass |
| | | Size 7 ½ | 95±6mm | Size 7 ½ | Pass |
| | | Size 8 | 102±6mm | Size 8 | Pass |
| | | Size 8 ½ | 108±6mm | Size 8 ½ | Pass |
| | | Size 9 | 114±6mm | Size 9 | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | To determine finger thickness | Minimum 0.10mm for all sizes<br>AQL 4% | | Size 6 | Pass |
| | | | | Size 6 ½ | Pass |
| | | | | Size 7 | Pass |
| | | | | Size 7 ½ | Pass |
| | | | | Size 8 | Pass |
| | | | | Size 8 ½ | Pass |
| | | | | Size 9 | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | To determine palm thickness | Minimum 0.10mm for all sizes<br>AQL 4% | | Size 6 | Pass |
| | | | | Size 6 ½ | Pass |
| | | | | Size 7 | Pass |
| | | | | Size 7 ½ | Pass |
| | | | | Size 8 | Pass |
| | | | | Size 8 ½ | Pass |
| | | | | Size 9 | Pass |
| ASTM D3577-19, Standard Specification for Rubber Surgical Gloves | To determine cuff thickness | Minimum 0.10mm for all sizes<br>AQL 4% | | Size 6 | Pass |
| | | | | Size 6 ½ | Pass |
| | | | | Size 7 | Pass |
| | | | | Size 7 ½ | Pass |
| | | | | Size 8 | Pass |
| | | | | Size 8 ½ | Pass |
| | | | | Size 9 | Pass |
| ASTM D6124-06R17, Standard Test Method for Residual Powder on Medical Gloves | Less than 2mg/glove | Maximum 2mg/glove for all sizes | | Pass | |
| ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10- Tests for irritation and skin sensitization | Irritation | Under the conditions of the testing, not an irritant | | Pass | |
| ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10- Tests for irritation and skin sensitization | Sensitization | Under the conditions of the testing, not a sensitizer | | Pass | |
| ISO 10993-5:2009(E) | Cytotoxicity | Under the conditions of | | Pass | |

| | | | |
|---|---|---|---|
| Biological Evaluation of Medical Devices - Part 5-Tests for in-vitro Cytotoxicity | | the testing, non-cytotoxic | |
| ISO 10993-11:2017(E) Biological Evaluation of Medical Devices - Part 11- Tests for Systemic Toxicity and Biological Tests | Acute systemic toxicity | Under the conditions of the testing, no acute systemic toxicity | Pass |
| USP 41 <151>Pyrogen Test | Material mediated pyrogenicity | Under the conditions of the testing, non-pyrogenic | Pass |
| USP 42 <85> Bacterial Endotoxin Test | Bacterial endotoxin limits | Less than 20EU/glove | Pass |

**G. Summary of Clinical Performance Testing**

No clinical performance testing was performed in support of this submission.

**H. Conclusion**

The conclusion drawn from the nonclinical tests demonstrates that the subject device Sterile Nitrile Surgical Gloves Powder Free is as safe, as effective and performs as well or better than the legally marketed predicate device “PRIMUS NITRILE GLOVES” Sterile Nitrile Surgical Gloves Powder Free (K170515).