November 25, 2019

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

Re: K192329
Trade/Device Name: Blue Latex Examination Powder Free Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: August 24, 2019
Received: August 27, 2019

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192329

Device Name

Blue Latex Examination Powder Free Gloves

Indications for Use *(Describe)*

Blue Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand 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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510K SUMMARY
K192329
as required by 21 CFR § 807.92

A. APPLICANT INFORMATION

Applicant	JR Engineering & Medical Technologies (M) SDN.BHD.
Address	Lot 8 &10, Jalan Zurah 3, Lot 1 & 3, Jalan Zurah, 3A/1, Pusat Perindustrian 2, 44200 Rasa, Selangor Darul Ehsan, Malaysia.
Phone	+603-60572081
Fax	+603-60572181
E-mail	ganeshjrmt@gmail.com
Contact Person	Mr.Ganesan Subramaniam
Designation	Managing Director
Contact Number	+6012 224 6677
Contact Email	ganeshjrmt@gmail.com
Date Submitted	November 24th 2019

B. DEVICE IDENTIFICATION

Name of the device	Blue Latex Examination Powder Free Gloves
Product proprietary or trade name	Blue Latex Examination Powder Free Gloves
Common or usual name	Latex Examination Gloves Powder Free
Classification name	Patient Examination Glove
Device Classification	Class I
Product Code	LYY
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Legally Marketed devices that Equivalency is claimed	MCARE PF Powder-free Latex Examination Gloves
510 (K) Number	K141042
Regulatory Class	Class I
Product code	LYY

D. DESCRIPTION OF THE DEVICE:

Blue Latex Examination Powder Free Gloves are manufactured to meet all the current specifications listed under the ASTM Specification D 3578-05 (Reapproved 2015), Standard Specification for Rubber Examination Gloves. They are made from Natural Rubber Latex. These gloves are blue in color and are powder free.

E. INDICATIONS FOR USE/INTENDED USE OF THE DEVICE:

Blue Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.

F. TECHNOLOGICAL CHARACTERISTICS

<table>
<tr><td rowspan="2">CHARACTERSTICS</td><td rowspan="2">STANDARDS</td><td colspan="3">DEVICE PERFORMANCE</td><td rowspan="2">Comparison</td></tr>
<tr><td>PREDICATE</td><td colspan="2">SUBJECT</td></tr>
<tr><td>510(k) Number</td><td>---</td><td>K141042</td><td colspan="2">K192329</td><td></td></tr>
<tr><td>Name of device</td><td>---</td><td>MCARE PF Powder Free Latex Examination Gloves</td><td colspan="2">Blue Latex Examination Powder Free Gloves</td><td>---</td></tr>
<tr><td rowspan="7">Dimensions- Length</td><td rowspan="7">ASTMD3578-05 (Reapproved 2015)</td><td rowspan="7">Length > 230 mm</td><td colspan="2">Length > 230 mm</td><td rowspan="7">Similar</td></tr>
<tr><td>Size</td><td>Average</td></tr>
<tr><td>Small</td><td>304</td></tr>
<tr><td>Medium</td><td>304</td></tr>
<tr><td>Large</td><td>305</td></tr>
<tr><td>X-Large</td><td>305</td></tr>
<tr><td>XX-Large</td><td>305</td></tr>
<tr><td rowspan="7">Dimensions- Width</td><td rowspan="7">ASTMD3578-05 (Reapproved 2015)</td><td rowspan="7">Width Min 95+/-10 mm (for medium size)</td><td colspan="2">Width Min 95+/-10 mm (for medium size)</td><td rowspan="7">Similar</td></tr>
<tr><td>Size</td><td>Average</td></tr>
<tr><td>Small</td><td>84</td></tr>
<tr><td>Medium</td><td>94</td></tr>
<tr><td>Large</td><td>105</td></tr>
<tr><td>X-Large</td><td>114</td></tr>
<tr><td>XX-Large</td><td>123</td></tr>
<tr><td rowspan="8">Physical Properties- Tensile Strength</td><td rowspan="14">ASTMD3578-05 (Reapproved 2015)</td><td rowspan="14"><u>Before Ageing</u>
Tensile Strength > 18 Mpa
<u>After Ageing</u>
Tensile Strength > 14 Mpa</td><td colspan="2"><u>Before Ageing</u>
Tensile Strength > 18 Mpa</td><td rowspan="8">Similar</td></tr>
<tr><td>Size</td><td>Actual value</td></tr>
<tr><td>Small</td><td>33.0</td></tr>
<tr><td>Medium</td><td>32.9</td></tr>
<tr><td>Large</td><td>32.2</td></tr>
<tr><td>X-Large</td><td>31.9</td></tr>
<tr><td>XX-Large</td><td>31.1</td></tr>
<tr><td colspan="2"><u>After Ageing</u>
Tensile Strength > 14 Mpa</td><td rowspan="7">Similar</td></tr>
<tr><td>Size</td><td>Actual value</td></tr>
<tr><td>Small</td><td>30.0</td></tr>
<tr><td>Medium</td><td>30.6</td></tr>
<tr><td>Large</td><td>29.9</td></tr>
<tr><td>X-Large</td><td>29.7</td></tr>
<tr><td>XX-Large</td><td>28.2</td></tr>
</table>

<table>
<tr><th>CHARACTERSTICS</th><th>STANDARDS</th><th colspan="2">DEVICE PERFORMANCE</th><th>Comparison</th></tr>
<tr><th></th><th></th><th>PREDICATE</th><th>CURRENT</th><th></th></tr>
<tr><td>510(k) Number</td><td></td><td>K141042</td><td>K192329</td><td></td></tr>
<tr><td>Physical Properties- Ultimate Elongation</td><td>ASTMD3578-05 (Reapproved 2015)</td><td>Before Ageing
Ultimate Elongation > 650%
After Ageing
Ultimate Elongation >500%</td><td><u>Before Ageing</u>
Ultimate Elongation > 650%
Size: Actual value
Small: 1322
Medium: 1250
Large: 1392
X-Large: 1130
XX-Large: 1149
After Ageing
Ultimate Elongation > 500%
Size: Actual value
Small: 1046
Medium: 1122
Large: 1257
X-Large: 1011
XX-Large: 1110</td><td>Similar</td></tr>
<tr><td>Thickness</td><td>ASTMD3578-05 (Reapproved 2015)</td><td>Palm > 0.08 mm
Finger > 0.08 mm</td><td>Palm > 0.08 mm
Finger > 0.08 mm
Size | Palm (Actual value) | Finger (Actual value)
Small | 0.31 | 0.38
Medium | 0.31 | 0.38
Large | 0.31 | 0.38
X-Large | 0.31 | 0.38
XX-Large | 0.31 | 0.38</td><td>Similar</td></tr>
<tr><td>Powder Free Residue</td><td>ASTMDD6319-10 (Reapproved 2015)</td><td>≤2 mg/glove</td><td>≤2 mg/glove
Size: Residual powder content (mg/glove)
Small: 0.20
Medium: 0.21
Large: 0.22
X-Large: 0.22
XX-Large: 0.23</td><td>Similar</td></tr>
<tr><td rowspan="4">Biocompatibility</td><td>Primary Skin Irritation-ISO 10993-10:2010(E)</td><td>Under the condition of study, not an irritant</td><td colspan="2">Under the condition of study not an irritant</td><td>Same</td></tr>
<tr><td>Dermal Sensitization-ISO 10993-10:2010(E)</td><td>Under the conditions of the study, not a sensitizer</td><td colspan="2">Under the conditions of the study, not a sensitizer</td><td>Same</td></tr>
<tr><td>In vitro cytotoxicity ISO10993-5 :2009(E)</td><td>/</td><td colspan="2">Under the conditions of the study, cytotoxic which is to be expected as latex is the positive control for this test.</td><td>Different</td></tr>
<tr><td>Material mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151></td><td>Data Not available</td><td colspan="2">Under the conditions of the study, non-pyrogenic</td><td>---</td></tr>
</table>

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
		PREDICATE	CURRENT	
510(k) Number		K141042	K192329	
Water Tight (1000 ml)	ASTM D5151-06 (Reapproved 2015)	Passes	Passes AQL-2.5	Same
Intended use		The mCare Powder Free Latex Examination Blue Glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Blue Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Material	-	Natural Latex	Natural Latex	Identical
Color	-	Blue	Blue	Identical
Texture	-	Finger Texture	Finger texture	Identical
Size	ASTMD 3578-5 (Reapproved 2015)	Small, Medium, Large, X Large & XX Large	Small, Medium, Large, X Large & XX Large	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Non sterile	Non sterile	Same
Powder/Powder free	-	Powder free	Powder free	Same
Label and Labeling	FDA Label requirements	Meets FDA's label and labeling requirements	Meets FDA's label and labeling requirements	Same
Manufacturer(s)	-	Mercator Medical (Thailand) LTD	JR Engineering & Medical Technologies (M) SDN.BHD. Malaysia.	---

G. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the length of the gloves	Min 230 mm for all sizes	Small:-304 mm Medium:-304mm Large:-305mm X-Large:-305mm XX-Large:-305 mm
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the width of the gloves	Small:-80+/-6 mm Medium:-95+/-6mm Large:-105+/-6 mm X-Large:-114+/-6 mm XX-Large:-120 +/-6 mm	Small:-84 mm Medium:-94 mm Large:-105 mm X-Large:-114 mm XX-Large:-123 mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the thickness of the gloves	Palm 0.08 mm min Finger 0.08 mm min for all sizes	Size Small Medium Large X-Large XX-Large	Palm 0.31mm 0.31mm 0.31mm 0.31mm 0.31mm	Finger 0.38mm 0.38mm 0.38mm 0.38mm 0.38mm
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 18Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all sizes	**Size** Small Medium Large X-Large XX-Large	**Before ageing** 33Mpa 32.9Mpa 32.2Mpa 31.9Mpa 31.1Mpa	**After ageing** 30Mpa 30.6Mpa 29.9Mpa 29.7Mpa 28.2Mpa
	To Determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 650% Min for all sizes **After Ageing** Ultimate Elongation 500% Min for all sizes	**Size** Small Medium Large X-Large XX-Large	**Before ageing** 1322% 1250% 1392% 1130% 1149%	**After ageing** 1046% 1122% 1257% 1011% 1110%
	To Determine the physical properties-stress at 500% Elongation	**Before Ageing** 5.5 Mpa Max for all sizes	**Size** Small Medium Large X-Large XX-Large	**Before ageing** 5.1 Mpa 5.2 Mpa 5.2 Mpa 5.1 Mpa 5.2 Mpa	**NA**
ASTM D5151-06 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 1.5		
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 Mg/Glove Max	**Size** Small Medium Large X-Large XX-Large	**Residual Powder Content** 0.20 mg/glove 0.21 mg/glove 0.22 mg/glove 0.22 mg/glove 0.23 mg/glove	
ASTM D 5712-95 (Re approved 2010) Standard Test Method for the Analysis of Protein in Natural Rubber	To determine the extractable protein in the gloves.	200 µg/ dm^2 Max for all sizes	**Size** Small Medium Large X-Large XX-Large	**Extractable Protein content** 45 µg/ dm^2 44 µg/ dm^2 44 µg/ dm^2 43 µg/ dm^2 45 µg/ dm^2	

The performance test data of the non-clinical tests meet following standards:

ASTMD 3578-5 (Reapproved 2015) Standard Specification for Rubber Examination Gloves

ASTM D5151-06 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves

ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves

ASTM D 5712-95 (Re approved 2010) Standard Test Method for the Analysis of Protein in Natural Rubber

H. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K192329, Blue Latex Examination Powder Free Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device K141042.