November 5, 2021

Bestsafe Glove CO., LTD.
Piyawat Chirasakulkarun
Chief Executive Officer
52/43 Wat Khot Hin-Khao Phai Road, T. Tubma
Muang Rayong, Rayong 21000
Thailand

Re: K210253
Trade/Device Name: Best Glove-Latex Powder Free Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: May 25, 2021
Received: August 30, 2021

Dear Piyawat Chirasakulkarun:

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 Clarence W. Murray, III, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K210253

Device Name

BEST GLOVE -LATEX POWDER FREE EXAMINATION GLOVE

Indications for Use *(Describe)*
A powder-free patient examination 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

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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510(k) SUMMARY

K210253

Latex Powder Free Examination Glove

1.0 Applicant Information

Applicant:	BESTSAFE GLOVE CO., LTD
Address	52/43 Watkodhin-Kaophai Rd. T. Tubma, A. Muang Rayong Rayong. THAILAND 21000
Phone Number:	+66 (038)-949880
Fax Number:	+66 (038)-949850
Name of Contact Person:	Piyawat Chirasakulkarun
Contact Number:	+66 81 4022099
Contact Email:	sales@bestsafe.co.th
Preparation date:	September 6, 2021

2.0 Device Identification:

Trade/Proprietary Name(s):	BEST GLOVE -LATEX POWDER FREE EXAMINATION GLOVE
Common Name:	Latex Powder Free Examination Gloves
Classification Name:	Patient Examination Gloves
510(k):	K210253
Device Class:	I
Product Code:	LYY
Registration Number	21 CFR 880.6250
Review Panel	General Hospital

3.0 Predicate Device

Device Name:	MPXX^{TM} Powder Free Natural Rubber Latex Examination Gloves
Manufacturer:	Total Glove Company Sdn. Bhd.
510(k):	K110250
Device Class:	I
Product Code:	LYY

4.0 Description of the Device:

Latex Examination Powder Free Gloves are manufactured to meet all the current specifications listed under the ASTM Specification D3578 - 19, Standard Specification for Rubber Examination Gloves. They are made from Natural Rubber Latex. These gloves are natural in color (no color is added) and are powder free.

5.0 Indication for Use of the Device:

A powder-free patient examination 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

6.0 Comparison of Technological characteristics between predicate and subject devices

Characteristics	References/Standards	Device performance		Comparison
		Predicate	Current	
510(k) Number	-	K110250	K210253	---
Manufacturer(s)	-	Total Glove Company Sdn. Bhd.	BESTSAFE GLOVE CO., LTD	---
Name of device	-	MPXX™ Powder Free Natural Rubber Latex Examination Gloves	BEST GLOVE -LATEX POWDER FREE EXAMINATION GLOVE	---
Indication for Use	Medical Gloves Guidance Manual, Issued on January 22, 2008	MPXX™ Powder Free Natural Rubber Latex Examination Gloves are single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare and the patient.	A powder-free patient Examination 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	Same
Material	ASTM D3578-19	Natural Rubber Latex	Natural Rubber Latex	Identical
Color		Natural Colo	Natural Colo	Same
Size	Medical Glove Guidance Manual-Labeling- Issued on January 22, 2008	Extra Small Small Medium Large Extra Large	Small Medium Large Extra Large	Different

<table>
<tr><th rowspan="2">Characteristics</th><th rowspan="2">References/Standards</th><th colspan="4">Device performance</th><th rowspan="2">Comparison</th></tr>
<tr><th>Predicate</th><th colspan="3">Current</th></tr>
<tr><td>Single Use</td><td>Medical Gloves Guidance Manual - Issued on January 22, 2008</td><td>Single use</td><td colspan="3">Single use</td><td>Same</td></tr>
<tr><td>Sterile/Non-sterile</td><td>-</td><td>Non-sterile</td><td colspan="3">Non-sterile</td><td>Same</td></tr>
<tr><td rowspan="7">Dimension</td><td rowspan="7">ASTM D3578-19</td><td rowspan="2"><u>Length</u>
230 mm minimum</td><td colspan="3"><u>Length</u>
230 mm min</td><td rowspan="2">Similar</td></tr>
<tr><td>Size</td><td>Actual value</td></tr>
<tr><td>Small</td><td>240</td><td rowspan="5"></td></tr>
<tr><td>Medium</td><td>240</td></tr>
<tr><td>Large</td><td>240</td></tr>
<tr><td>Extra Large</td><td>241</td></tr>
<tr><td rowspan="7"><u>Width</u>
No data is available</td><td colspan="3"><u>Width</u>
Medium: 95 mm ± 10 mm
(for Medium size)</td><td rowspan="7">Different</td></tr>
<tr><td colspan="2">Size</td><td>Actual value</td></tr>
<tr><td colspan="2">Small</td><td>85</td></tr>
<tr><td colspan="2">Medium</td><td>93</td></tr>
<tr><td colspan="2">Large</td><td>105</td></tr>
<tr><td colspan="2">Extra Large</td><td>115</td></tr>
<tr><td>Thickness</td><td>ASTM D3578-19</td><td>Finger = 0.08 mm. min
Palm = 0.08 mm. Min</td><td colspan="3">Finger = 0.08 mm. min
Palm = 0.08 mm. Min</td><td>Similar</td></tr>
<tr><td rowspan="5"></td><td colspan="3"></td><td rowspan="5"></td></tr>
<tr><td>Size</td><td>Palm
(Actual value)</td><td>Finger
(Actual value)</td></tr>
<tr><td>Small</td><td>0.09</td><td>0.12</td></tr>
<tr><td>Medium</td><td>0.09</td><td>0.12</td></tr>
<tr><td>Large</td><td>0.10</td><td>0.13</td></tr>
<tr><td>Extra Large</td><td>0.09</td><td>0.12</td></tr>
</table>

<table>
<tr><th rowspan="2">Characteristics</th><th rowspan="2">References/Standards</th><th colspan="3">Device performance</th><th rowspan="2">Comparison</th></tr>
<tr><th>Predicate</th><th colspan="2">Current</th></tr>
<tr><td rowspan="15">Physical Properties</td><td rowspan="15">ASTM D3578-19</td><td rowspan="8"><u>Before Aging</u>
Tensile Strength
18 MPa min
<u>After Aging</u>
Tensile Strength
14 MPa min</td><td colspan="2"><u>Before Aging</u>
Tensile Strength (18 MPa min)</td><td>Similar</td></tr>
<tr><td>Size</td><td>Actual value</td><td rowspan="5"></td></tr>
<tr><td>Small</td><td>18.04</td></tr>
<tr><td>Medium</td><td>19.13</td></tr>
<tr><td>Large</td><td>18.26</td></tr>
<tr><td>Extra Large</td><td>18.64</td></tr>
<tr><td colspan="2"><u>After Aging</u>
Tensile Strength (14 MPa min)</td><td rowspan="6">Similar</td></tr>
<tr><td>Size</td><td>Actual value</td></tr>
<tr><td>Small</td><td>15.02</td></tr>
<tr><td>Medium</td><td>18.12</td></tr>
<tr><td>Large</td><td>16.01</td></tr>
<tr><td>Extra Large</td><td>15.06</td></tr>
<tr><td rowspan="8"><u>Before Aging</u>
Ultimate Elongation
650% min
<u>After Aging</u>
Ultimate Elongation
500% min (after aging)</td><td colspan="2"><u>Before Aging</u>
Ultimate Elongation : 650% min</td><td rowspan="6">Similar</td></tr>
<tr><td>Size</td><td>Actual value</td></tr>
<tr><td>Small</td><td>651</td></tr>
<tr><td>Medium</td><td>654</td></tr>
<tr><td>Large</td><td>650</td></tr>
<tr><td>Extra Large</td><td>650</td></tr>
<tr><td colspan="2"><u>After Aging</u>
Ultimate Elongation : 500% min</td><td rowspan="6">Similar</td></tr>
<tr><td>Size</td><td>Actual value</td></tr>
<tr><td>Small</td><td>501</td></tr>
<tr><td>Medium</td><td>601</td></tr>
<tr><td>Large</td><td>501</td></tr>
<tr><td>Extra Large</td><td>502</td></tr>
</table>

Characteristics	References/Standards	Device performance			Comparison
		Predicate	Current		
Water Tight Test (1000 ml)	ASTM D5151 – 19	Pass AQL 1.5	Pass AQL 1.5		Same
Powder Residual	ASTM D6124-06 (Reapproved 2017)	Meet ≤ 2.0 mg/glove	≤ 2.0 mg/glove		Similar
			Size	Residual powder content (mg/glove)	
			Small	0.62	
			Medium	0.46	
			Large	0.61	
			Extra Large	0.61	
Biocompatibility	Primary Skin Irritation – ISO 10993-10 Third Edition 2010-08-01	Not a primary skin irritant under the conditions of the study	Not a primary skin irritant under the conditions of the study		Same
	Dermal Sensitization – ISO 10993-10 Third Edition 2010-08-01	Not a contact sensitizer under the conditions of the study	Not a contact sensitizer under the conditions of the study		Same
	In vitro cytotoxicity ISO10993-5 :2009(E)	No data is available	Under the conditions of the study cytotoxic for undiluted (neat) and 1:2 dilutions but noncytotoxic for 1:4, 1:8, 1:16 and 1:32 dilutions. Moreover, under the conditions of the study, non acute systemic toxic.		Different
	Acute Systemic Toxicity ISO10993-11:2017(E)	No data is available	Under the conditions of the study, did not induce any systemic toxicity.		Different

7.0 Summary of Non-clinical performance Tests

Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Dimension	ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the length of the gloves	Min 230 mm for all sizes	Small: 240 mm Medium: 240 mm Large: 240 mm Extra Large: 241 mm	Pass
	ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To determine the width of the gloves	Small: 80 ± 10 mm Medium: 95+/-10mm Large: 111± 10 mm Extra Large: 120 ± 10 mm	Small: 85 mm Medium: 93 mm Large: 105 mm Extra Large: 115 mm	Pass
	ASTM D3578-19 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	Small: Palm 0.09 mm, Finger: 0.12 mm Medium: Palm: 0.09 mm, Finger: 0.12 mm Large: Palm 0.10 mm, Finger: 0.13 mm Extra Large: Palm 0.09 mm, Finger: 0.12 mm	Pass
Physical Properties	ASTM D3578-19 Standard Specification for Rubber Examination Gloves	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 18Mpa Minimal for all sizes **After Ageing** Tensile Strength 14Mpa Minimal for all sizes	**Before Ageing** Small: 18.04 MPa Medium: 19.13 MPa Large: 18.26 MPa Extra Large: 18.64 MPa **After ageing**: Small: 15.02 MPa Medium: 18.12 MPa Large: 16.01 MPa Extra Large: 15.06 MPa	Pass

Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Physical Properties	ASTM D3578-19 Standard Specification for Rubber Examination Gloves	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	**Before Ageing** Small: 651% Medium: 654 % Large:650% Extra Large:650% **After ageing**: Small:501% Medium: 601% Large:501% Extra Large:502%	Pass
Watertight test	ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	Sample size: 200 pcs Inspection level : GI AQL 1.5 Acceptance Number 7 Rejection Number 8	The batch size for this sampling is 35,001-150,000. Hence, according to the single sampling plan GI, the sample to be drawn is under code L equivalent to 200 pcs with accept 7 and reject 8 to be accept under AQL 1.5. Small: 0 (Zero) Medium: 0 (Zero) Large:0 (Zero) Extra Large:0 (Zero)	Pass
Residual powder	ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 mg per glove or less	Sample size : 5 pcs Requirement: 2 mg per glove or less Result : Small:0.62 mg/glove Medium: 0.46 mg/glove Large: 0.61 mg/glove Extra Large:0.61 mg/glove	Pass

Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Protein content	ASTM D5712 - 15, Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber.	To determine the extractable protein in the gloves	Less than 200 µg/dm^2	Sample size : 3 pcs Requirement: Less than 200 µg/dm^2 Result : Small:124.36 µg /dm^2 Medium: 140.78 µg /dm^2 Large: 134.26 µg /dm^2 Extra 159.46 µg /dm^2	Pass

The performance test data of the non-clinical tests meet following standards:
ASTM D 3578 – 19 Standard Specification for Rubber Examination Gloves
ASTM D 5151-19: 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 D5712 – 15, Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber.

8.0 Summary of Clinical Performance Tests:

Not Applicable

9.0 Conclusion:

The conclusion drawn from the non-clinical tests demonstrates that the subject device Latex Examination Powder Free Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device K110250

--END--