



August 20, 2021

Careplus (M) SDN BHD  
Lim Shyan  
CEO/ Managing Director  
Lot 120 & 121, Jalan Senawang 3, Senawang Industrial Estate  
Seremban, Negeri Sembilan 70450  
Malaysia

Re: K203705

Trade/Device Name: Latex Examination Glove, Powder free with Protein Content Labeling Claim (50 ug/g or less of total extractable Protein)  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Non-Powdered Patient Examination Glove  
Regulatory Class: Class I, reserved  
Product Code: LYY  
Dated: July 19, 2021  
Received: July 21, 2021

Dear Lim Shyan:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Liqun Zhao -S

For Clarence W. Murray III, PhD  
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

## Indications for Use

510(k) Number (if known)

K203705

Device Name

Latex Examination Glove, Powder free with Protein Content Labeling Claim (50 µg/g or less of total extractable protein)

Indications for Use (Describe)

A 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.

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## **510(K) SUMMARY**

Applicant: CAREPLUS (M) SDN BHD

Address: Lot 120 & 121, Jalan Senawang 3,  
Senawang Industrial Estate,  
70450 Seremban,  
Negeri Sembilan Darul Khusus,  
Malaysia.

Phone No. 60-6-6772781 Fax No. 60-6-6772780

Contact Person Lim Kwee Shyan

Date of Summary 13<sup>th</sup> July, 2021

### **Device Information**

Trade Name: Latex Examination Glove, Powder free with Protein Content Labeling  
Claim (50 µg/g or less of total extractable protein)

Common Name: Patient Examination Gloves

Classification Name: Patient Examination Gloves

### **Device Description**

The device is a class I latex patient examination gloves 21 CFR 880.6250, Patient Examination Glove, LYY made by surface treatment on the inner and anti-tack coating on outer surface. The process modifies the surface characteristics that assist the user in donning the gloves with ease without the use of any dusting or donning powder is substantially equivalent in safety and effectiveness to the predicate device.

They are ambidextrous and come in different sizes, Extra Small, Small, Medium, Large and Extra Large.

### **Predicate device**

The device and the predicate device, Latex Examination Gloves, Powder Free, 510(k) number K152593, share the same intended use, same material and same compliance with standards. The only difference in this submission is to include the Protein Labelling Claim (50 µg/g or less of total extractable protein) with no changes in the manufacturing process and product design.

### **Indication for Use**

A 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.

Technological comparison Table:

| Characteristics                                                                                                                                                                                                                  | Standard Reference       | ASTM Specifications                                                                                                           | Subject Device Measured Values (510(k) K203705)                                                                                                                    | Predicate Device K152593                                                                                                                                       | Characteristics      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <u>Dimension</u><br>Length, mm<br><br>Thickness (palm), mm<br>Thickness (finger), mm<br>Width (size: X-Small), mm<br>Width (size: Small), mm<br>Width (size: Medium), mm<br>Width (size: Large), mm<br>Width (size: X-Large), mm | ASTM D3578               | XS, S- 220min.<br>M, L-230 min.<br>XL- NA<br>0.08min.<br>0.08 min.<br>70 ± 10<br><br>80 ± 10<br>95 ± 10<br><br>111 ± 10<br>NA | min. 240mm<br>min. 240mm<br>min. 240mm<br>min. 0.13mm<br>min. 0.14mm<br>75mm-76mm<br><br>84mm-86mm<br>96mm- 97mm<br><br>107-108mm<br>117-119mm                     | Meet Specification<br>Meet Specification<br><br>Meet Specification<br><br>Meet Specification<br>Meet Specification<br>Meet Specification<br>Meet Specification | Same                 |
| Physical Properties (Before Aging)<br>i) Tensile Strength, Mpa<br>ii) Stress at 500% Elongation<br>iii) Ultimate Elongation (After Aging)<br>i) Tensile Strength, Mpa<br>ii) Ultimate Elongation,                                | ASTM D3578               | 18 min.<br>5.5 MPa max.<br><br>650 min.<br><br>14 min.<br>500 min.                                                            | min. 24 Mpa<br>max.3.3Mpa<br><br>min. 750%<br><br>min. 18Mpa<br>min. 750%                                                                                          | Meet Specification<br><br><br>Meet Specification                                                                                                               | Same<br><br><br>Same |
| Protein Content                                                                                                                                                                                                                  | ASTM D3578<br>ASTM D5712 | 200 µg/dm <sup>2</sup> max.                                                                                                   | 50 µg/g and below                                                                                                                                                  | Meet Specification                                                                                                                                             | Same                 |
| Freedom from holes                                                                                                                                                                                                               | ASTM D3578<br>ASTM D5151 | G-1, AQL 2.5                                                                                                                  | 2.5 and below                                                                                                                                                      | Meet Specification                                                                                                                                             | Same                 |
| Residual Powder                                                                                                                                                                                                                  | ASTM D3578<br>ASTM D6124 | 2 mg/glove max.                                                                                                               | 2 mg/glove and below                                                                                                                                               | Meet Specification                                                                                                                                             | Same                 |
| <b>Biocompatibility Test</b>                                                                                                                                                                                                     |                          | <b>ISO10993-10</b>                                                                                                            |                                                                                                                                                                    |                                                                                                                                                                |                      |
| Skin Irritation Test                                                                                                                                                                                                             | n.a                      | n.a                                                                                                                           | Passed                                                                                                                                                             |                                                                                                                                                                | Same                 |
| Dermal Sensitization Test                                                                                                                                                                                                        | n.a                      | n.a                                                                                                                           | Passed                                                                                                                                                             |                                                                                                                                                                | Same                 |
| Acute Systemic Study                                                                                                                                                                                                             |                          | ISO10993-11                                                                                                                   | Acute Systemic Toxicity study.<br>Conclusion: Under the conditions of this study, the test material both inner and outer surface did not reveal systemic toxicity. |                                                                                                                                                                | Same                 |

| No. | Characteristic                                                                                                                                                                                    | Subject Device, K203705<br>Latex Examination Gloves, Powder Free with Protein<br>Content Labeling Claim (50 µg/g or less of total<br>extractable protein )                                          | Predicate Device<br>K152593                         |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| 1   | Product Code                                                                                                                                                                                      | LYY                                                                                                                                                                                                 | Same                                                |
| 2   | Regulation Number                                                                                                                                                                                 | 21 CFR 880.6250                                                                                                                                                                                     | Same                                                |
| 3   | Device Class                                                                                                                                                                                      | Class 1                                                                                                                                                                                             | Same                                                |
| 4   | Indication for Use                                                                                                                                                                                | A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.                         | Same                                                |
| 5   | Design                                                                                                                                                                                            | Powder Free, Non-Sterile, Ambidextrous, Beaded Cuff                                                                                                                                                 | Same                                                |
| 6   | Construction                                                                                                                                                                                      | Ambidextrous, Powder Free Latex                                                                                                                                                                     | Same                                                |
| 7   | Color                                                                                                                                                                                             | Natural                                                                                                                                                                                             | Same                                                |
| 8   | Materials                                                                                                                                                                                         | Latex                                                                                                                                                                                               | Same                                                |
| 9   | Single Use                                                                                                                                                                                        | Single use only                                                                                                                                                                                     | Same                                                |
| 10  | Packaging                                                                                                                                                                                         | Packed in Dispenser Boxes                                                                                                                                                                           | Same                                                |
| 11  | Performance<br>I) Freedom From Holes<br>II) Dimension<br>III) Physical Properties<br>IV) Residual Powder<br>V) Biocompatibility Test<br>Primary Skin Irritation Test<br>Dermal Sensitization Test | Meets ASTM D 3578<br>Meets ASTM D 3578<br>Meets ASTM D 3578<br>Meets ASTM D 3578<br><br>Under the conditions of the study, not an irritant.<br>Under the conditions of the study, not a sensitizer. | Same<br>Same<br>Same<br>Same<br>Same<br>Same        |
| 12  | Labeling Claim                                                                                                                                                                                    | i) No Chemotherapy Drugs Labeling Claim<br>ii) With Protein Labeling Claim                                                                                                                          | i) Same<br>ii) Different. No Protein Labeling Claim |

Summary of Non-Clinical Testing

The performance test data of the non-clinical test demonstrates that the subject device met the specifications and the acceptance criteria of the test method or standards shown in the table below:

| Test Methodology         | Purpose                                          | Acceptance Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                  | Results                 |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
|--------------------------|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------|----|-------------------------|---|------------------|---------------------|---------------------------|------------------|---------------------|-------------|-----------|--------------------|-------------|-----------|------|--|----|--------|------|------|--|--|--|----------------|----|----|----|-----|----|------|
| ASTM D3578<br>ASTM D5151 | Freedom From Holes                               | Meet requirement inspection level G-I, AQL 2.5                                                                                                                                                                                                                                                                                                                                                                                                       | Pass                    |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| ASTM D3578               | Dimension                                        | <table><tr><td>Size</td><td>XS</td><td>S</td><td>M</td><td>L</td><td>XL</td></tr><tr><td>Length, min. mm</td><td colspan="2">220</td><td colspan="2">230</td><td>NA</td></tr><tr><td>Thickness, min. mm</td><td colspan="4" rowspan="2">0.08</td><td rowspan="2">NA</td></tr><tr><td>finger</td></tr><tr><td>palm</td><td colspan="4">0.08</td></tr><tr><td>Width, ± 10 mm</td><td>70</td><td>80</td><td>95</td><td>111</td><td>NA</td></tr></table> | Size                    | XS                  | S  | M                       | L | XL               | Length, min. mm     | 220                       |                  | 230                 |             | NA        | Thickness, min. mm | 0.08        |           |      |  | NA | finger | palm | 0.08 |  |  |  | Width, ± 10 mm | 70 | 80 | 95 | 111 | NA | Pass |
| Size                     | XS                                               | S                                                                                                                                                                                                                                                                                                                                                                                                                                                    | M                       | L                   | XL |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| Length, min. mm          | 220                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 230                     |                     | NA |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| Thickness, min. mm       | 0.08                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                         |                     | NA |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| finger                   |                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                         |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| palm                     | 0.08                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                         |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| Width, ± 10 mm           | 70                                               | 80                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 95                      | 111                 | NA |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| ASTM D3578               | Physical Properties                              | <table><tr><th colspan="3">Before Aging</th><th colspan="2">After Accelerated Aging</th></tr><tr><td>Tensile Strength</td><td>Ultimate Elongation</td><td>Stress at 500% Elongation</td><td>Tensile Strength</td><td>Ultimate Elongation</td></tr><tr><td>18 MPa min.</td><td>650% min.</td><td>5.5 MPa min.</td><td>14 MPa min.</td><td>500% min.</td></tr></table>                                                                                 | Before Aging            |                     |    | After Accelerated Aging |   | Tensile Strength | Ultimate Elongation | Stress at 500% Elongation | Tensile Strength | Ultimate Elongation | 18 MPa min. | 650% min. | 5.5 MPa min.       | 14 MPa min. | 500% min. | Pass |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| Before Aging             |                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                      | After Accelerated Aging |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| Tensile Strength         | Ultimate Elongation                              | Stress at 500% Elongation                                                                                                                                                                                                                                                                                                                                                                                                                            | Tensile Strength        | Ultimate Elongation |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| 18 MPa min.              | 650% min.                                        | 5.5 MPa min.                                                                                                                                                                                                                                                                                                                                                                                                                                         | 14 MPa min.             | 500% min.           |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| ASTM D3578<br>ASTM D6124 | Powder Content                                   | Not more than 2mg per glove                                                                                                                                                                                                                                                                                                                                                                                                                          | Pass                    |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| ASTM D3578<br>ASTM D5712 | Protein Content                                  | This glove contains 50 µg/g or less per glove of total aqueous extractable protein                                                                                                                                                                                                                                                                                                                                                                   | Pass                    |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| ISO10993-10              | Biocompatibility<br>Primary Skin Irritation Test | Not a skin irritant under the conditions of test.                                                                                                                                                                                                                                                                                                                                                                                                    | Pass                    |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
|                          | Dermal Sensitization Test                        | Not a skin sensitizer under the conditions of test                                                                                                                                                                                                                                                                                                                                                                                                   |                         |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |
| ISO 10993-11             | Biocompatibility<br>Acute Systemic Toxicity      | Did not reveal systemic toxicity under the conditions of test.                                                                                                                                                                                                                                                                                                                                                                                       | Pass                    |                     |    |                         |   |                  |                     |                           |                  |                     |             |           |                    |             |           |      |  |    |        |      |      |  |  |  |                |    |    |    |     |    |      |

Summary of Clinical Testing

Clinical testing is not applicable to this device.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject in 510(k) K203705, Latex Examination Glove, Powder free with Protein Content Labeling Claim (50  $\mu$ g/g or less of total extractable protein) is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.