May 27, 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: K202765
Trade/Device Name: ENCORE Latex Textured Surgical Gloves, Powder Free with Protein Content Labeling Claim (50 micrograms or less) and Tested for use with Chemotherapy drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: April 13, 2021
Received: April 16, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ryan Ortega, PhD
Acting 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)*
K202765

Device Name
ENCORE® Latex Textured Surgical Gloves, Powder free with Protein Content Labeling Claim (50 micrograms or less) and Tested for use with Chemotherapy drugs, Non-Pyrogenic

Indications for Use *(Describe)*
Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy:

Test Chemotherapy Drug (Concentration)	Minimum Breakthrough Detection Time in minutes
Fluorouracil (50.0mg/ml)	>240
Etoposide (20.0mg/ml)	>240
Cyclophosphamide (20.0mg/ml)	>240
Carmustine (3.3mg/ml)	13.2
Thiotepa (10.0mg/ml)	12.0
Paclitaxel (6.0mg/ml)	>240
Doxorubicin Hydrochloride (2.0mg/ml)	>240
Methotrexate (25.0mg/ml)	>240
Vincristine Sulfate (1.0mg/ml)	>240

"WARNING: Do not use Carmustine and Thiotepa"

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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K202765

510(K) SUMMARY

1.0 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

2.0 Date of Summary 11th May, 2021

3.0 Device Information

Device Name: ENCORE® Latex Textured Surgical Gloves, Powder free with Protein Content Labeling Claim (50 micrograms or less) and Tested for use with Chemotherapy drugs, Non-Pyrogenic

Common Name: Surgical Gloves
Product Code: KGO
Subsequent Product Code: LZC
Classification Name: Surgeon's Gloves
Patient Examination Gloves Specialty (21 CFR 88.6250, LZC)

4.0 Device Description

It is the powder-free variation of the class I sterile latex surgical gloves made by on-line polymer and anti-tack coating on inner and outer surface. The process modifies the surface characteristics and causes it to remain tack-free without the use of any dusting or donning powder. The device size comes in different sizes – 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0. Gloves meet the specification of ASTM D3577 with dimension as below:

Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Length, min. mm	245	265						
Thickness, min. mm	0.10							
Width, ± 6 mm	70	76	83	89	95	102	108	114

5.0 Predicate Device

K983489, Encore Mark IV Powder Free Surgical Gloves (Protein Labeling Claim), Ansell Perry. The device is a class I, Surgeon's Gloves, KGO, LZC powder-free..

6.0 Indication for Use

Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect aa surgical wound from contamination.

7.0 Technological Comparison Table:

Characteristics	**ASTM Specification**	**Standard References**	**Subject Glove K202765 (**ENCORE® Latex Textured Surgical Gloves, Powder free with Protein Content Labeling Claim (50 micrograms or less and Tested for use with Chemotherapy drugs, Non-Pyrogenic)	**Predicate Device (**Encore Mark IV Powder Free Surgical Gloves, Protein Labeling Claim, K983489)	**Discussion**
Freedom from holes	ASTM D3577 ASTM D5151	G-I, AQL 1.5	Meets ASTM D3577 Meets ASTM D5151	Meets ASTM D3577 Meets ASTM D5151	Same
<u>Dimension</u> Length (size: 5.5), mm Length (size: 6.0), mm Length (size: 6.5), mm Length (size: 7.0), mm Length (size: 7.5), mm Length (size: 8.0), mm Length (size: 8.5), mm Length (size: 9.0), mm Thickness (cuff), mm Thickness (palm), mm Thickness (finger), mm Width (size: 5.5), mm Width (size: 6.0), mm Width (size: 6.5), mm Width (size: 7.0), mm Width (size: 7.5), mm Width (size: 8.0), mm Width (size: 8.5), mm Width (size: 9.0), mm	ASTM D3577	 245 min 265 min 265 min 265 min 265 min 265 min 265 min 265 min 0.10 min 0.10 min 0.10 min 70 ± 6 76 ± 6 83 ± 6 89 ± 6 95 ± 6 102 ± 6 108 ± 6 114 ± 6	 min. 295 min. 295 min. 296 min. 295 min. 296 min. 296 min. 297 min. 295 min. 0.158 min. 0.220 min. 0.225 73-75 mm 78-79 mm 83-84 mm 90-91 mm 96-97 mm 102-103 mm 107-109 mm 114-115 mm	 Meet 245mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 0.10mm min Meet 0.10mm min Meet 0.10mm min Meet 70 ± 6 mm Meet 76 ± 6 mm Meet 83 ± 6 mm Meet 89 ± 6 mm Meet 95 ± 6 mm Meet 102 ± 6 mm Meet 108 ± 6 mm Meet 114 ± 6 mm	Same
Physical Properties (Before Ageing) i) Tensile Strength (Mpa) ii) Ultimate Elongation (%) iii) Stress at 500% Elongation (After Ageing) i) Tensile Strength (Mpa) ii) Ultimate Elongation (%)	 ASTM D3577	 Min. 24 Min. 750 Max. 5.5 Min. 18 Min. 560	 min. 24 min. 780 max. 2.0 min. 20 min. 880	 Meets ASTM D3577 Meets ASTM D3577	 Same Same
Powder Content	ASTM D3577 ASTM D6124	Max. 2 mg/glove	Max. 0.57 mg/glove	Meets ASTM D3577 Meets ASTM D6124	Same

Biocompatibility Test i) Primary Skin Irritation Test	ISO 10993-10	No Animal Irritation	Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Same
ii) Dermal Sensitization Test	ISO 10993-10	No Animal Irritation	Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.	Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.	Same
iii) In vitro Cytotoxicity Test	ISO 10993-5		Conclusions: Under the conditions of this study, the test material is cytotoxic (grade 4) at undiluted, 1:2, 1:4, 1:8 dilutions; and Non-cytotoxic, grade 2 at 1:16 dilution, grade 0 at 1:32 and 1:64 dilutions	iii) No data available	Different
iv) Acute Systemic Toxicity	ISO 10993-11		Conclusion: Under the conditions of this study, the test material both inner and outer surface did not reveal systemic toxicity.	iv) No data available	Different
Protein Label Claim			Contains 50 micrograms or less of total water extractable protein per gram.	Contains 50 micrograms or less of total water extractable protein per gram.	Same
Chemo Drugs Claim	ASTM D6978	-	Chemo Claim	No Chemo Claim	Different
Non- Pyrogenic Claim	ISO 10993-12	-	Non-Pyrogenic	No Non-Pyrogenic claim	Different
Color	-	-	Natural	Natural	Same
White Pigment	-	-	Titanium Dioxide	Titanium Dioxide	Same
Intended Use	-	-	Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.	Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.	Same

Chemotherapy Drug	**ASTM D6978-05**	**Subject Glove** (ENCORE® Latex Textured Surgical Gloves, Powder free with Protein Content Labeling Claim (50 micrograms or less) and Tested for use with Chemotherapy drugs, Non-Pyrogenic)
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**
Fluorouracil (Adrucil)	50.0mg/ml	> 240
Etoposide (Toposar)	20.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
*Carmustine (BCNU)	3.3mg/ml	13.2
*Thiotepa	10.0mg/ml	12.0
Paclitaxel (Taxol)	6.0mg/ml	> 240
Doxorubicin Hydrochloride	2.0mg/ml	> 240
Methotrexate	25.0mg/ml	> 240
Vincristine Sulfate	1.0mg/ml	> 240

8.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical test that support a determination of substantial equivalence are the same as mentioned immediately above (ASTM requirement).

Following standards were used for the testing:

- ASTM D3577-09 Standard Specification for Rubber Surgical Gloves
- ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D5712-15 Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method
- ASTM D7160-16 Standard Practice for Determination of Expiration Dating for Medical Gloves
- ASTM D6978-16 Standard Assessment of Resistance of Medical Devices to Permeation
- ISO 11137-2:2013 Sterilization of Healthcare Products- Establishing the sterilization dose

9.0 Summary of Clinical Testing

Clinical data is not needed for medical gloves or of most devices cleared by the 510(k) process.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.