DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 16, 2015

Careplus (M) SDN BHD
Mr. Lim Kwee Shyan
Managing Director
Lot 120 & 121 Jalan Senawang 3
Senawang Industrial Estate
70450 Seremban
Negeri Sembilan Darul Khusus
MALAYSIA

Re: K142862
Trade/Device Name: Powder Free Nitrile Examination Glove, Blue (Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient examination glove
Regulatory Class: I
Product Code: LZA
Dated: December 1, 2014
Received: December 3, 2014

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142862

Device Name: Powder Free Nitrile Examination Glove, Blue (Colored)

Indications 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.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

CAREPLUS (M) SDN BHD (Company No. 212677-K)
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Quality and Relationship You Can Trust

510(K) SUMMARY **510(k) No.: K142862**

1.0 Applicant: CAREPLUS (M) SDN BHD

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Senawang Industrial Estate,
70450 Seremban,
Negeri Sembilan Darul Khusus,
Malaysia.
Phone No.: 60-6-6772781 Fax No. 60-6-6772780

2.0 Contact Person: Lim Kwee Shyan
Phone No.: 60-6-6772781 Fax No. 60-6-6772780

3.0 Preparation Date: 16th January, 2015

4.0 Device Information
Device Name: **POWDER FREE NITRILE EXAMINATION GLOVE, BLUE(COLORED)**
Common Name: POWDER FREE NITRILE EXAMINATION GLOVE
Classification Name: Patient Examination Gloves

5.0 Claim of Equivalence
The device is a class I latex patient examination gloves 21 CFR 880.6250, Patient Examination Glove, LZA which is made powder-free by a process of on-line polymer-coating and chlorination which is substantially equivalent in safety and effectiveness to the predicate device Powder Free Nitrile Examination Glove Blue and White Colored, Non-sterile 510(k) number K123469, product code LZA.

6.0 Device Description
It is the powder-free variation of the class I latex patient examination gloves made by on-line polymer-coating and on-line chlorination process. The process modifies the surface characteristics and causes it to remain tack-free without the use of any dusting or donning powder. It is particularly suitable to users who prefer a powder-free work environment or who may be sensitive to the powdered version of the same gloves.

7.0 Intended Use of Device
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.

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8.0 1)Comparison To Predicate Device

No.	Characteristic	Standards	Related Defects	Predicate Device (Powder Free Nitrile Examination Glove, Blue and White Colored K123469)	Powder-Free Nitrile Examination Glove (Blue Color)
1	Water Tight Test, 1000 ml	ASTM D6319-10 ASTM D5151-06	G- I, AQL 2.5 (FDA GII, AQL 2.5)	Meets ASTM D6319-10 Meets ASTM D5151-06	Meets ASTM D6319-10 Meets ASTM D5151-06
2	Physical Properties (Before Ageing) i) Tensile Strength(Mpa) ii)Ultimate Elongation(%) (After Ageing) i) Tensile Strength(Mpa) ii) Ultimate Elongation(%)	ASTM D6319-10	Min. 14 Min. 500 Min. 14 Min. 400	Meets ASTM D6319-10 Meets ASTM D6319-10 Meets ASTM D6319-10 Meets ASTM D6319-10	Meets ASTM D6319-10 Meets ASTM D6319-10 Meets ASTM D6319-10 Meets ASTM D6319-10
3	Powder Content	ASTM D6319-10 ASTM D6124-06	Max. 2mg/glove	Meets ASTM D6319-10 Meets ASTM D6124-06	Meets ASTM D6319-10 Meets ASTM D6124-06
4	Biocompatibility Test i) Primary Skin Irritation Test ii)Dermal Sensitization Test	ISO 10993-10 As per 16CFR Part 1500	No Animal Irritation No Animal Irritation	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study, the test material did not cause an irritant response. ii)Dermal Sensitization Test. Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study, the test material did not cause an irritant response. ii)Dermal Sensitization Test. Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.
5	Color Extraction			Blue	Blue

Conclusions:
Careplus (M) Sdn Bhd, Powder Free Nitrile Examination Glove, Blue (colored) is similar with Wear Safe (M) Sdn Bhd, Powder Free Nitrile Examination Glove, Blue and White Colored, K123469.

2) Summary of Technological Characteristics of the Device

Powder Free Nitrile Examination Glove, Blue(Colored) possesses the following technological characteristic (as compared to ASTM or equivalent standards):

Parameter	Standard References	Device Performance
Dimensions	ASTM D6319-10	Meet Specification
Physical Properties	ASTM D6319-10	Meet Specification
Freedom from pin-holes	ASTM D5151-06 ASTM D6319-10	Meet Specification Meet Specification
Powder Free Residue	ASTM D6124-06 ASTM D6319-10	Meet Specification Meet Specification
Biocompatability Test	Dermal Sensitization Test (ISO 10993-10:2010)	Not a contact skin sensitizer
	Primary Skin Irritation Test (As per 16CFR Part 1500)	Not a primary skin irritant

9.0 Conclusion

Powder Free Nitrile Examination Glove, Blue(Colored) performs according to the glove performance standards referenced in Section 8.0 above. The device is substantially equivalent to current marketed devices per Section 5.0.