November 13, 2017

Central Medicare Sdn. Bhd.
Arivalagan Subramaniam
QA/RA Manager
PT 2609 - 2620, BT 8, Jalan Changkat Jong
Teluk Intan, 36000 MALAYSIA

Re: K172525
Trade/Device Name: Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZC, LZA
Dated: August 15, 2017
Received: August 21, 2017

Dear Arivalagan Subramaniam:

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 (DICE) 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" (21 CFR 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 (DICE) 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K172525

Device Name

Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*

Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Gloves have been tested for use with chemotherapy drugs using ASTM D6978-05 and will be labeled with a statement of compliance and a summary of the testing results.

Chemotherapy Drug Permeation

The following chemicals have been tested with these gloves:

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (minutes)
*Carmustine (3.3 mg/ml)	Min minutes before breakthrough = 12.4
Cisplatin (1.0 mg/ml)	No breakthrough for up to 240 minutes
Cyclophosphamide (20 mg/ml)	No breakthrough for up to 240 minutes
Doxorubicin HCl (2.0 mg/ml)	No breakthrough for up to 240 minutes
Etoposide (20.0 mg/ml)	No breakthrough for up to 240 minutes
Fluorouracil (50.0 mh/ml)	No breakthrough for up to 240 minutes
Mitoxantrone (2.0 mg/ml)	No breakthrough for up to 240 minutes
Paclitaxel (6.0 mg/ml)	No breakthrough for up to 240 minutes
*Thiotepa (10.0 mg/ml)	Min minutes before breakthrough = 24.4
Dacarbazine (10.0 mg/ml)	No breakthrough for up to 240 minutes
Ifosfamide (50.0 mg/ml)	No breakthrough for up to 240 minutes
Vincristine Sulfate (1.0 mg/ml)	No breakthrough for up to 240 minutes

* Please note that the following drugs have extremely low permeation times:

Carmustine: 12.4 minutes and Thiotepa: 24.4 minutes

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

510(k) Number: K172525

Date Prepared: 13th October 2017

1.0 Submitter:

Name:	Arivalagan Subramaniam QA/RA Manager
Address:	Central Medicare Sdn. Bhd. PT 2609-2620, Batu 8, Jalan Changkat Jong, 36000 Teluk Intan, Perak, Malaysia
Contact:	Tel: +605-629 0000 Fax: +605-629 0001
510(k) Submission Prepared by:	Muhammad Abdul Rahman Regulatory Affairs Officer Central Medicare Sdn. Bhd.

2.0 Name of the device:

Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs

Common Names:	Chemotherapy Gloves, Exam Gloves
Device Class:	Class I
Classification Names:	Patient Examination Gloves Specialty (21 CFR 880.6250 product code LZC, LZA)

3.0 Identification of the Legally Marketed Devices that equivalency is claimed:

Trade Name:	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs
510k Number:	K172525

4.0 Description of the Device:

Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous, and come in different sizes – Extra Small, Small, Medium, Large and Extra Large.

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510(k) Summary

Gloves meet the specification of ASTM D6319-10 and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978-05, as guide lined by the FDA Medical Glove Guidance Manual.

5.0 Intended Use of the Device:

Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Gloves have been tested for use with chemotherapy drugs using ASTM D6978-05 and will be labeled with a statement of compliance and a summary of the testing results.

Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves:

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (minutes)
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Etoposide (20.0 mg/ml)	No breakthrough for up to 240 minutes
Fluorouracil (50.0 mh/ml)	No breakthrough for up to 240 minutes
Mitoxantrone (2.0 mg/ml)	No breakthrough for up to 240 minutes
Paclitaxel (6.0 mg/ml)	No breakthrough for up to 240 minutes
*Thiotepa (10.0 mg/ml)	Min minutes before breakthrough = 24.4
Dacarbazine (10.0 mg/ml)	No breakthrough for up to 240 minutes
Ifosfamide (50.0 mg/ml)	No breakthrough for up to 240 minutes
Vincristine Sulfate (1.0 mg/ml)	No breakthrough for up to 240 minutes

* Please note that the following drugs have extremely low permeation times:
Carmustine: 12.4 minutes and Thiotepa: 24.4 minutes

6.0 Summary of the Technological Characteristics of the Device:

The proposed and predicate devices all share the same technological characteristics and design by meeting ASTM D6319-10 and following the FDA's Medical Glove Guidance Manual.

The purpose of this submission is to demonstrate that the proposed device is substantially equivalent, to a legally marketed predicate device, a specialty chemotherapy glove, Hebei Hongsen Plastics Technology Co, Ltd's POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146). The proposed device will be known as Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs.

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510(k) Summary

Biocompatibility studies were performed on the proposed device. Under the conditions of the study, the proposed device is not a sensitizer, or an irritant.

The proposed and predicate devices are made of nitrile synthetic latex. The proposed device have similar technological characteristics compared to the predicate devices, as both devices meet ASTM D6319-10 and follow FDA's Medical Glove Guidance Manual.

The technological characteristics and design for the proposed device have been assessed and confirmed that the standard specifications and performance are appropriate for the requirements of powder free nitrile examination gloves and specialty chemotherapy gloves.

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs of the proposed and predicate devices.

General Comparison Table:

	Proposed Device	Predicate Device	Remark
Sponsor	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Hebei Hongsen Plastics Technology Co, Ltd**	
Trade Name	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs	Similar
510k Number	K172525	K163146	
Product Code	LZA, LZC	LZA, LZC	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Blue	Blue	Similar
Labeling Information	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Same
Chemotherapy Drug Permeation Claim	Fluorouracil, Etoposide (Toposar), Cyclophosphamid (Cytoxan), Carmustine (BCNU), Thiotepa, Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin, Ifosfamide, Mitoxantrone, Vincristine Sulfate	Fluorouracil, Etoposide (Toposar), Cyclophosphamid (Cytoxan), Carmustine (BCNU), Thiotepa, Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin, Carboplatin, Docetaxel, Ifosfamide, Irinotecan, Mechlorethamine HCL, Methotrexate, Mitomycin C, Mitoxantrone, Vincristine Sulfate	Similar

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510(k) Summary

Device Dimensions Table:

Proposed Device							
Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs		Size					Tolerance
		XS	S	M	L	XL	
	Length	minimum 230					
	Width (mm)	70	80	95	110	120	±0.10
	Thickness (mm)						
	Cuff	0.06					±0.03
	Palm	0.08					±0.03
	Finger	0.10					±0.03
Predicate Device							
POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (163146)		Size					Tolerance
		XS	S	M	L	XL	
	Length	minimum 230					
	Width (mm)	70	80	95	110	120	±0.10
	Thickness (mm)						
	Cuff	0.06					±0.03
	Palm	0.08					±0.03
	Finger	0.10					±0.03

Performance Comparison Table:

Item			Proposed Device	Predicate Device	Remark
			Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs	
Color			Blue	Blue	Similar
Physical Properties	Before Aging	Tensile Strength	15 Mpa min	15 Mpa min	Same
		Ultimate Elongation	500% min	500% min	Same
	After Aging	Tensile Strength	14 Mpa min	14 Mpa min	Same
		Ultimate Elongation	400% min	400% min	Same
Freedom from Holes			In accordance with ASTM D5151-06, following ASTM D6319 AQL 2.5/Inspection Level G-I	Be free from holes when tested in accordance with ASTM D5151 AQL 1.5	Similar
Powder Content			Max. 0.52 mg per glove	Max. 0.32 mg per glove	Similar

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Chemotherapy Permeation Comparison Claim:

Chemotherapy Drug Testing - ASTM D6978-05				Remark
Proposed Device		Predicate Device		
Tested Chemotherapy Drug and Concentration	**Minimum Breakthrough Detection Time (minutes)**	**Tested Chemotherapy Drug and Concentration**	**Average Breakthrough Detection Time (minutes)**	
Fluorouracil (50.0 mh/ml)	No breakthrough for up to 240 minutes	Fluorouracil (50.0 mh/ml)	No breakthrough for up to 240 minutes	Same
Etoposide (20.0 mg/ml)	No breakthrough for up to 240 minutes	Etoposide (20.0 mg/ml)	No breakthrough for up to 240 minutes	Same
Cyclophosphamide (20 mg/ml)	No breakthrough for up to 240 minutes	Cyclophosphamide (20 mg/ml)	No breakthrough for up to 240 minutes	Same
Carmustine (3.3 mg/ml)	Min minutes before breakthrough = 12.4	Carmustine (3.3 mg/ml)	Min minutes before breakthrough = 45.0	Similar
Thiotepa (10.0 mg/ml)	Min minutes before breakthrough = 24.4	Thiotepa (10.0 mg/ml)	Min minutes before breakthrough = 30.0	Similar
Paclitaxel (6.0 mg/ml)	No breakthrough for up to 240 minutes	Paclitaxel (6.0 mg/ml)	No breakthrough for up to 240 minutes	Same
Doxorubicin HCl (2.0 mg/ml)	No breakthrough for up to 240 minutes	Doxorubicin HCl (2.0 mg/ml)	No breakthrough for up to 240 minutes	Same
Dacarbazine (10.0 mg/ml)	No breakthrough for up to 240 minutes	Dacarbazine (10.0 mg/ml)	No breakthrough for up to 240 minutes	Same
Cisplatin (1.0 mg/ml)	No breakthrough for up to 240 minutes	Cisplatin (1.0 mg/ml)	No breakthrough for up to 240 minutes	Same
Carboplatin (10.0 mg/ml)	Not Tested	Carboplatin (10.0 mg/ml)	No breakthrough for up to 240 minutes	Will not be claimed
Docetaxel (10.0 mg/ml)	Not Tested	Docetaxel (10.0 mg/ml)	No breakthrough for up to 240 minutes	Will not be claimed
Ifosfamide (50.0 mg/ml)	No breakthrough for up to 240 minutes	Ifosfamide (50.0 mg/ml)	No breakthrough for up to 240 minutes	Same
Irinotecan (20.0 mg/ml)	Not Tested	Irinotecan (20.0 mg/ml)	No breakthrough for up to 240 minutes	Will not be claimed
Mechlorethamine HCL (1.0 mg/ml)	Not Tested	Mechlorethamine HCL (1.0 mg/ml)	No breakthrough for up to 240 minutes	Will not be claimed
Methotrexate (25.0 mg/ml)	Not Tested	Methotrexate (25.0 mg/ml)	No breakthrough for up to 240 minutes	Will not be claimed
Mitomycin C (0.5 mg/ml)	Not Tested	Mitomycin C (0.5 mg/ml)	No breakthrough for up to 240 minutes	Will not be claimed
Mitoxantrone (2.0 mg/ml)	No breakthrough for up to 240 minutes	Mitoxantrone (2.0 mg/ml)	No breakthrough for up to 240 minutes	Same
Vincristine Sulfate (1.0 mg/ml)	No breakthrough for up to 240 minutes	Vincristine Sulfate (1.0 mg/ml)	No breakthrough for up to 240 minutes	Same

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510(k) Summary

7.0 Non-Clinical Performance Data

The proposed device and its predicate devices share the same intended use, are made of the same material, are within the same minimum specifications of thickness and length by meeting ASTM D6319-10, similar permeation rates for chemotherapy drugs as per ASTM D6978-05, similar labeling, physical properties, freedom from powder, biocompatibility and water tightness.

The above test results demonstrated that the proposed device complies with the following standards: ASTM D6319.10

8.0 Clinical Performance Data

N/A

9.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the proposed device is substantially equivalent to the predicate device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146).