March 5, 2018

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

Re: K173942
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: December 27, 2017
Received: January 2, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173942

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	Concentrate(mg/ml)	Minimum Breakthrough Detection Time (minutes)
Bleomycin Sulfate	15	>240
Busulfan	6	>240
Carboplatin	10	>240
Carmustine	3.3	12.4
Cisplatin	1	>240
Chloroquine	50	>240
Cyclophosphamide	20	>240
Cyclosporin	100	>240
Cytarabine HCI	100	>240
Dacarbazine	10	>240
Daunorubicin HCI	5	>240
Docetaxel	10	>240
Doxorubicin Hydrochloride	2	>240
Epirubicin (Ellence)	2	>240
Etoposide	20	>240
Fludarabine	25	>240
Fluorouracil	50	>240
Gemcitabine	38	>240
Idarubicin	1	>240
Ifosfamide	50	>240
Irinotecan	20	>240
Mechlorethamine HCI	1	>240
Melphalan	5	>240
Methotrexate	25	>240
Mitomycin	0.5	>240
Mitoxantrone	2	>240
Oxaliplatin	5	>240
Paclitaxel	6	>240
Paraplatin	10	>240
Retrovir	10	>240
Rituximab	10	>240
Thiotepa	10	24.4
Topotecane	1	>240

Trisonex	1	>240
Velcade	1	>240
Vincristine Sulfate	1	>240

*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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Tel: +605 629 0000 Fax: +605 629 0001

510(k) Summary

510(k) Number: K173942

Date Prepared: 5th March 2018

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
510(k) Number:	K173942
Predicate Device 510(k) 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.
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.

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5.0 Indications for Use

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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	Concentrate (mg/ml)	Minimum Breakthrough Detection Time (minutes)
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Cisplatin	1	>240
Chloroquine	50	>240
Cyclophosphamide	20	>240
Cyclosporin	100	>240
Cytarabine HCI	100	>240
Dacarbazine	10	>240
Daunorubicin HCI	5	>240
Docetaxel	10	>240
Doxorubicin Hydrochloride	2	>240
Epirubicin (Ellence)	2	>240
Etoposide	20	>240
Fludarabine	25	>240
Fluorouracil	50	>240
Gemcitabine	38	>240
Idarubicin	1	>240
Ifosfamide	50	>240
Irinotecan	20	>240
Mechlorethamine HCI	1	>240
Melphalan	5	>240
Methotrexate	25	>240
Mitomycin	0.5	>240
Mitoxantrone	2	>240
Oxaliplatin	5	>240
Paclitaxel	6	>240
Paraplatin	10	>240
Retrovir	10	>240
Rituximab	10	>240
Thiotepa	10	24.4
Topotecane	1	>240
Trisonex	1	>240
Velcade	1	>240
Vincristine Sulfate	1	>240

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510(k) Summary

*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 gain premarket clearance for the proposed device as a specialty chemotherapy glove and patient examination glove by proving substantial equivalence to Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K172525) as a predicate device. The proposed device will also be known as Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs.

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)**	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Same**
Trade Name	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	Same
510k Number	K173942	K172525	
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.	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.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Blue	Blue	Same
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

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510(k) Summary

Chemotherapy Drug Permeation Claim:

	Proposed Device	Predicate Device	Remark
Sponsor	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Same**
Chemotherapy Drug Permeation Claim	Bleomycin Sulfate, Busulfan, Carboplatin, Carmustine, Cisplatin, Chloroquine, Cyclophosphamide, Cyclosporin, Cytarabine HCl, Dacarbazine, Daunorubicin HCl, Docetaxel, Doxorubicin Hydrochloride, Epirubicin (Ellence), Etoposide, Fludarabine, Fluorouracil, Gemcitabine, Idarubicin, Ifosfamide, Irinotecan, Mechlorethamine HCl, Melphalan, Methotrexate, Mitomycin, Mitoxantrone, Oxaliplatin, Paclitaxel, Paraplatin, Retrovir, Rituximab, Thiotepa, Topotecane, Trisonex, Velcade and Vincristine Sulfate	Fluorouracil, Etoposide (Toposar), Cyclophosphamid (Cytoxan), Carmustine (BCNU), Thiotepa, Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin, Ifosfamide, Mitoxantrone, Vincristine Sulfate	Proposed Device Tested 24 More Drugs

Device Dimensions Table:

Proposed Device							
Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K173942)		**Size**					**Tolerance**
		XS	**S**	**M**	**L**	**XL**	
	Length (mm)	minimum 230					
	Width (mm)	70	80	95	110	120	±10
	Thickness (mm)						
	Cuff	0.06					±0.03
	Palm	0.08					±0.03
	Finger	0.10					±0.03
Predicate Device							
Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K172525)		**Size**					**Tolerance**
		XS	**S**	**M**	**L**	**XL**	
	Length (mm)	minimum 230					
	Width (mm)	70	80	95	110	120	±10
	Thickness (mm)						
	Cuff	0.06					±0.03
	Palm	0.08					±0.03
	Finger	0.10					±0.03

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Performance Comparison Table:

Item			Proposed Device	Predicate Device	Remark
			Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K173942)	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K172525)	
Color			Blue	Blue	Same
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	In accordance with ASTM D5151-06, following ASTM D6319 AQL 2.5/Inspection Level G-I	Same
Powder Content			Avg. 0.44 mg per glove	Avg. 0.52 mg per glove	Same

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510(k) Summary

Chemotherapy Permeation Comparison Claim:

Chemotherapy Drug Testing - ASTM D6978-05				
Tested Chemotherapy Drug	Concentrate (mg/ml)	Proposed Device	Predicate Device	Remark
		Minimum Breakthrough Detection Time (minutes)		
Bleomycin Sulfate	15	>240	Not Tested	Additional
Busulfan	6	>240	Not Tested	Additional
Carboplatin	10	>240	Not Tested	Additional
Carmustine	3.3	12.4	12.4	Same
Cisplatin	1	>240	>240	Same
Chloroquine	50	>240	Not Tested	Additional
Cyclophosphamide	20	>240	>240	Same
Cyclosporin	100	>240	Not Tested	Additional
Cytarabine HCl	100	>240	Not Tested	Additional
Dacarbazine	10	>240	>240	Same
Daunorubicin HCl	5	>240	Not Tested	Additional
Docetaxel	10	>240	Not Tested	Additional
Doxorubicin Hydrochloride	2	>240	>240	Same
Epirubicin (Ellence)	2	>240	Not Tested	Additional
Etoposide	20	>240	>240	Same
Fludarabine	25	>240	Not Tested	Additional
Fluorouracil	50	>240	>240	Same
Gemcitabine	38	>240	Not Tested	Additional
Idarubicin	1	>240	Not Tested	Additional
Ifosfamide	50	>240	>240	Same
Irinotecan	20	>240	Not Tested	Additional
Mechlorethamine HCl	1	>240	Not Tested	Additional
Melphalan	5	>240	Not Tested	Additional
Methotrexate	25	>240	Not Tested	Additional
Mitomycin	0.5	>240	Not Tested	Additional
Mitoxantrone	2	>240	>240	Same
Oxaliplatin	5	>240	Not Tested	Additional
Paclitaxel	6	>240	>240	Same
Paraplatin	10	>240	Not Tested	Additional
Retrovir	10	>240	Not Tested	Additional
Rituximab	10	>240	Not Tested	Additional
Thiotepa	10	24.4	24.4	Same
Topotecane	1	>240	Not Tested	Additional
Trisonex	1	>240	Not Tested	Additional
Velcade	1	>240	Not Tested	Additional
Vincristine Sulfate	1	>240	>240	Same

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510(k) Summary

7.0 Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above, and all mentioned devices follow ASTM D6319-10 requirements and FDA's Medical Glove Guidance Manual.

The proposed device and it's 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 and by following the same guidance – FDA's Medical Glove Guidance Manual. Therefore, the proposed device is substantially equivalent to the predicate.

The test results demonstrated that the proposed device complies with the following standards:

ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.
Guidance for Industry and FDA Staff Medical Glove Guidance Manual (Document issued on January 22, 2008)
The following standards were followed to carry out the testing:
ASTM D5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves.
ISO 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension
ASTM D7160-16 Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D573 - 04 Standard Test Method for Rubber—Deterioration in an Air Oven
ASTM D6978-05 (Reapproved 2013), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

8.0 Based on Assessment of Clinical Performance Data

N/A

9.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K172525).