DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 20, 2016

WRP Asia Pacific Sdn. Bhd.
Sarala Devi Jayaraman
Regulatory Affairs Manager
Lot 1, Jalan 3,
Kaw Perusahaan Bandar Baru Salak Tinggi,
Sepang, 43900 MY

Re: K161422
Trade/Device Name: Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-sterile, Tested For Use With Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: September 15, 2016
Received: September 21, 2016

Dear Sarala Devi Jayaraman:

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" (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 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Division 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)*

Device Name
Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs

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.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

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

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Flourouracil (Adrucil)	50.0mg/ml	> 240
Etopside (Toposar)	20.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
*Carmustine (BCNU)	3.3mg/ml	15.0
*Thiotepa	10.0mg/ml	2.0
Paclitaxel (Taxol)	6.0mg/ml	> 240
Doxorubicin Hydrochloride (Adriamycin)	2.0mg/ml	> 240
Dacarbazine	10.0mg/ml	> 240
Cisplatin	1.0mg/ml	> 240
Ifosfamide	50.0mg/ml	> 240
Mitoxantrone	2.0mg/ml	> 240
Vincristine Sulfate	1.0mg/ml	> 240
Methotrexate	25mg/ml	> 240
Mitomycin C	0.5mg/ml	> 240

* Please note that the-following drugs have extremely low permeation times:
Carmustine (BCNU) : 15 minutes and Thiotepa : 2 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1.0 Submitter:

Name: Sarala Devi Jayaraman
Address: WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.: +60 3 8706 1486
Fax No.: +60 3 8706 1485

Date of Summary Prepared: 17 October 2016

2.0 Name of the modified device Identification:

Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile,
Tested for use with Chemotherapy Drugs
Common Name: Exam Gloves
Classification Name: Patient Examination Gloves Specialty (21 CFR 880.6250 product code LZC)
Patient Examination Gloves (21 CFR 880.6250 product code LZA)

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

	Predicate
Manufacturer	WRP Asia Pacific Sdn Bhd
Device name	Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-sterile, Tested for use with Chemotherapy Drugs (and various brandnames)
510(k) Number	K141982
MDL	D236305
Regulatory Class	I
Product Code	LZC, LZA

4.0 Description of The Device:

Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile meets all the requirements of ASTM standard D6319-10, D6978-05 and FDA 21 CFR 880.6250.

The powder free nitrile examination glove is manufactured from synthetic rubber latex. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder on the glove surface. The glove is ambidextrous, i.e. can be worn on right hand or left hand. The physical properties of glove i.e. tensile strength meet ASTM standard D6319-10.

510(k) SUMMARY

5.0 Indications of 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.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

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

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Flourouracil (Adrucil)	50.0mg/ml	> 240
Etopside (Toposar)	20.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
*Carmustine (BCNU)	3.3mg/ml	15.0
*Thiotepa	10.0mg/ml	2.0
Paclitaxel (Taxol)	6.0mg/ml	> 240
Doxorubicin Hydrochloride (Adriamycin)	2.0mg/ml	> 240
Dacarbazine	10.0mg/ml	> 240
Cisplatin	1.0mg/ml	> 240
Ifosfamide	50.0mg/ml	> 240
Mitoxantrone	2.0mg/ml	> 240
Vincristine Sulfate	1.0mg/ml	> 240
Methotrexate	25 mg/ml	> 240
Mitomycin C	0.5 mg/ml	> 240

* Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU) : 15 minutes and Thiotepa : 2 minutes

510(k) SUMMARY

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Blue Nitrile Examination Gloves, Non-Sterile are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards as shown in Table 1.

Chemotherapy claim is similar to Predicate, which has a glove thickness below 0.10mm and is shorter than 270mm but compliant with the ASTM standards.

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
Manufacturer(s)		WRP Asia Pacific Sdn Bhd	WRP Asia Pacific Sdn Bhd
510(k) Number		K141982	K161422
Dimensions	ASTM D6319-10	Min 240mm	Min 240mm
Physical Properties	ASTM D6319-10	Meets	Meets
Thickness - Finger - Palm - Cuff	ASTM D6319-10	0.07 – 0.10mm 0.07 – 0.09mm 0.06 – 0.08mm	0.07 – 0.10mm 0.07 – 0.09mm 0.06 – 0.08mm
Powder Free	ASTM D6124-06 (≤ 2 mg/glove)	Meets	Meets
Chemotherapy Drug Permeation Test	ASTM D6978-05		
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**	
Flourouracil (Adrucil)	50.0mg/ml	> 240	> 240
Etopside (Toposar)	20.0mg/ml	> 240	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240	> 240
*Carmustine (BCNU)	3.3mg/ml	15.0	15.0
*Thiotepa	10.0mg/ml	2.0	2.0
Paclitaxel (Taxol)	6.0mg/ml	> 240	> 240
Doxorubicin Hydrochloride (Adriamycin)	2.0mg/ml	> 240	> 240
Dacarbazine	10.0mg/ml	> 240	> 240
Cisplatin	1.0mg/ml	> 240	> 240
Ifosfamide	50.0mg/ml	> 240	> 240
Mitoxantrone	2.0mg/ml	> 240	> 240
Vincristine Sulfate	1.0mg/ml	> 240	> 240
Methotrexate	25 mg/ml	-	> 240
Mitomycin C	0.5 mg/ml	-	> 240
Warning Statement		* WARNING: Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) : 15 minutes and Thiotepa : 2 minutes.	* WARNING: Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) : 15 minutes and Thiotepa : 2 minutes.

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010(E)	Passes Not a primary skin irritant under the conditions of the study.	Passes Not a primary skin irritant under the conditions of the study.
	Dermal Sensitization - ISO 10993-10:2010(E)	Passes Not a contact sensitizer under the conditions of the study.	Passes Not a contact sensitizer under the conditions of the study.
Watertight (1000ml)	ASTM D5151-06	Passes	Passes
Intended 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.	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.
Material	ASTM D6319-10	Nitrile	Nitrile
Color	-	Blue	Blue
Texture	-	Finger textured	Finger textured
Size	ASTM D6319-10	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Glove Guidance Manual - Labeling	Single use	Single use

510(k) SUMMARY

7.0 Substantial Equivalent 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 (ASTM Requirements).

The device and the predicate share the same intended use, same material, same specifications for thickness and length, similar permeation rates for chemotherapy drugs, similar labeling according to the glove guidance, and same compliance with standards for physical properties, powder free, biocompatibility and water tightness. Thus, the device is substantial equivalent to the predicate.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not needed for this device.

9.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the subject device is substantially equivalent to the predicate device K141982.