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

March 29, 2017

Dipped Products (Thailand) Limited
% Indraj Bamrah
Senior Regulatory Consultant
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K161929
Trade/Device Name: Palm-Pro Nitrile Powder Free Examination Glove, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: February 8, 2017
Received: February 10, 2017

Dear Indraj Bamrah:

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,

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)*
K161929

Device Name
Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs

Indications for Use *(Describe)*
The Palm-pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove has also been tested for use with Chemotherapy Drugs.

The following Chemotherapy drugs have been tested for use with these gloves in accordance with ASTM D6978-05:

Chemotherapy drug (concentration)	Breakthrough Detection Time
Dacarbazine (10,000 ppm)	No breakthrough up to 240 minutes
*Carmustine (BCNU) (3,300 ppm)	Breakthrough at 30.6 minutes
Cyclophosphamide (20,000 ppm)	No breakthrough up to 240 minutes
Doxorubicin Hydrocloride (2,000 ppm)	No breakthrough up to 240 minutes
Fluorrouracil (5,000 ppm)	No breakthrough up to 240 minutes
Cisplatin (1,000 ppm)	No breakthrough up to 240 minutes
Etoposide (20,000 ppm)	No breakthrough up to 240 minutes
Paclitaxel (6,000 ppm)	No breakthrough up to 240 minutes
Thiotepa (10,000 ppm)	Breakthrough at 181.3 minutes

*Please note that the following drug has extremely low permeation times:
Carmustine (BCNU): 30.6 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.

Section 5 – 510(k) Summary

Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs

K161929

1. Submission Sponsor

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2. Submission Correspondent

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Email: project.management@emergogroup.com

3. Date Prepared

February 8, 2017

4. Device Identification

Trade/Proprietary Name:	Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs
Common/Usual Name:	Patient Examination Glove
Classification Name:	Patient Examination Glove
Regulation Number:	880.6250
Product Code:	LZA, Polymer Patient Examination Glove
	LZC, Patient Examination Glove, Specialty
Device Class:	Class I
Classification Panel:	General Hospital

5. Legally Marketed Predicate Device(s)

K141982, Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs, WRP Asia Pacific Sdn Bhd.

6. Device Description

The Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs are patient examination gloves that worn by an examiner to prevent contamination between the patient and examiner. The gloves are suitable for use with Chemotherapy drugs, are ambidextrous and green in color. The gloves are supplied non-sterile, in boxes of 100 (measured by weight), intended for single use and are disposable.

7. Indication for Use Statement

The Palm-pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove has also been tested for use with Chemotherapy Drugs.

The following Chemotherapy drugs have been tested for use with these gloves in accordance with ASTM D6978-05:

Chemotherapy drug (concentration)	Breakthrough Detection Time
Dacarbazine (10,000 ppm)	No breakthrough up to 240 minutes
*Carmustine (BCNU) (3,300 ppm)	Breakthrough at 30.6 minutes

Cyclophosphamide (20,000 ppm)	No breakthrough up to 240 minutes
Doxorubicin Hydrocloride (2,000 ppm)	No breakthrough up to 240 minutes
Fluorrouracil (5,000 ppm)	No breakthrough up to 240 minutes
Cisplatin (1,000 ppm)	No breakthrough up to 240 minutes
Etoposide (20,000 ppm)	No breakthrough up to 240 minutes
Paclitaxel (6,000 ppm)	No breakthrough up to 240 minutes
Thiotepa (10,000 ppm	Breakthrough at 181.3 minutes

*Please note that the following drug has extremely low permeation times:
Carmustine (BCNU): 30.6 minutes.

8. Substantial Equivalence Discussion

The following table compares the Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	Dipped Products (Thailand) Ltd	WRP Asia Pacific Sdn Bhd	**Significant Differences**
Trade Name	Palm-Pro Powder Free Nitrile Examination Glove, tested for use with Chemotherapy drugs	Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs	
510(k) Number	K161929	K141982	
Product Code	LZC LZA	LZC LZA	Same
Regulation Number	880.6250	880.6250	Same
Regulation Name	Patient Examination Glove	Patient Examination Glove	Same
Indications for Use	The Palm-pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs is a non-sterile disposable device intended for medical purposes that is worn on the	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	Similar

Manufacturer	Dipped Products (Thailand) Ltd	WRP Asia Pacific Sdn Bhd	**Significant Differences**
Trade Name	Palm-Pro Powder Free Nitrile Examination Glove, tested for use with Chemotherapy drugs	Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs	
	examiner's hand to prevent contamination between patient and examiner. The glove has also been tested for use with Chemotherapy Drugs. *Please note that the following drug has extremely low permeation times: Carmustine (BCNU): 30.6 minutes.	use with Chemotherapy Drugs. *Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 15 minutes and Thiotepa: 2 minutes.	
Permeation times for Chemotherapy drugs ***Chemotherapy Drug tested (concentration)***	***Breakthrough Detection time***		Similar. The subject device when tested with Carmustine and Thiotepa are found to have higher breakthro-ugh times than the predicate device. detection times
Dacarbazine (10,000 ppm)	No breakthrough up to 240 minutes	>240 minutes	
Carmustine (BCNU) (3,300 ppm)	Breakthrough at 30.6 minutes	15.0 minutes	
Cyclophosphamide (20,000 ppm)	No breakthrough up to 240 minutes	>240 minutes	
Doxorubicin Hydrochloride (2,000 ppm)	No breakthrough up to 240 minutes	>240 minutes	
Fluorouracil (5,000 ppm)	No breakthrough up to 240 minutes	>240 minutes	
Cisplatin (1,000 ppm)	No breakthrough up to 240 minutes	>240 minutes	
Etoposide (20,000 ppm)	No breakthrough up to 240 minutes	>240 minutes	
Paclitaxel (6,000 ppm)	No breakthrough up to 240 minutes	>240 minutes	
Thiotepa	Breakthrough at 181.3 minutes	2.0 minutes	

Manufacturer	Dipped Products (Thailand) Ltd	WRP Asia Pacific Sdn Bhd	**Significant Differences**
Trade Name	Palm-Pro Powder Free Nitrile Examination Glove, tested for use with Chemotherapy drugs	Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs	
(10,000 ppm)			
Material	Nitrile	Nitrile	Same
Single Use	Yes	Yes	Same
Dimensions	Overall length: 240mm min.	Overall length: 240mm min.	Same
Thickness Specification	Finger: 0.09 – 0.10mm Palm: 0.07 – 0.08mm	Finger: 0.07 – 0.10mm Palm: 0.07 – 0.09mm	Similar. The thickness specification of the subject device is within the bounds of that of the predicate device.
Physical Properties (ASTM D6319-10)	Meets requirements	Meets requirements	Same
Freedom from holes	Passes	Passes	Same
Residue Powder Test	Passes	Passes	Same
Color	Green	Blue	Similar. The green color does not raise new questions of safety and effectiveness.
Biocompatibility Skin Irritation (ISO 10993 – 10) Dermal Sensitization (ISO 10993 – 10)	Under the conditions of the study, the device was non-irritating Under the conditions of the study, the device was non-sensitizing	Not a primary skin irritant under the conditions of the study Not a contact sensitizer under the conditions of the study	Same

9. Non-Clinical Performance Data

As part of demonstrating that the Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs meets the required specifications and in showing substantial equivalence to the predicate device, Dipped Products (Thailand) Ltd. completed a number of non-clinical performance tests. The Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs meets all the requirements for overall design, performance and biocompatibility results confirming that the design output meets the design inputs and specifications for the device.

The Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-10: tests for dermal sensitization and primary skin irritation: For primary skin irritation: Under the conditions of the study, the device was non-irritating. For dermal sensitization: Under the conditions of the study, the device was non-sensitizing.
- Dimension tests in accordance with ASTM D6319-10: tests for palm width, overall length, palm thickness and finger thickness: **PASS**
- Water leak test in accordance with ASTM D6319-10: determination of AQL level: **PASS**
- Tensile strength and ultimate elongation in accordance with ASTM D6319-10: testing conducted pre-aging and after aging: **PASS**
- Powder content in accordance with ASTM D6319-10: residual powder content determined per glove: **PASS**
- Permeation Testing for Chemotherapy Gloves in accordance with ASTM D 6978-05: Break through time tested and reported for nine drugs.

10. Statement of Substantial Equivalence

The Palm-Pro Nitrile Powder Free Examination Glove, tested for use with Chemotherapy drugs, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device as it has the same intended use and similar technological characteristics as the previously cleared predicate device.