DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 13, 2017

Hebei Hongsen Plastics Technology Co, Ltd
% Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd.,liyuan,
Tongzhou District
Beijing, 101121 CN

Re: K163146
Trade/Device Name: POWDER FREE Blue Nitrile GLOVES, 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: January 3, 2017
Received: January 9, 2017

Dear Ray Wang:

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)*
K163146

Device Name
POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
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.
The proposed device was 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 proposed device.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Fluorouracil	50.0 mg/ml (50,000 ppm)	> 240
Etoposide (Toposar)	20.0 mg/ml (20,000 ppm)	> 240
Cyclophosphamid (Cytoxan)	20.0 mg/ml (20,000 ppm)	> 240
*Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	45.0
*Thiotepa	10.0 mg/ml (10,000 ppm)	30.0
Paclitaxel (Taxol)	6.0 mg/ml (6,000 ppm)	> 240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000 ppm)	> 240
Dacarbazine (DTIC)	10.0 mg/ml (10,000 ppm)	> 240
Cisplatin	1.0 mg/ml (1,000 ppm)	> 240
Carboplatin	10.0 mg/ml (10,000 ppm)	> 240
Docetaxel	10.0 mg/ml (10,000 ppm)	> 240
Ifosfamide	50.0 mg/ml (50,000 ppm)	> 240
Irinotecan	20.0 mg/ml (20,000 ppm)	> 240
Mechlorethamine HCL	1.0 mg/ml (1,000 ppm)	> 240
Methotrexate	25.0 mg/ml (25,000 ppm)	> 240
Mitomycin C	0.5 mg/ml (500 ppm)	> 240
Mitoxantrone	2.0 mg/ml (2,000 ppm)	> 240
Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	> 240

* Please note that the following drugs have low permeation times:
Carmustine (BCNU): 45 minutes and Thiotepa: 30 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

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K163146

1. Date of Preparation: 02/08/2017

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Proposed Device Identification

Trade Name: POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs
Device Name: NITRILE Patient Examination Gloves (Powder Free)
Common Name: Patient Examination Gloves

Regulatory Information

Classification: I
Product Code: LZA, LZC
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication for Use:
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.
The proposed device was 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
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Paclitaxel (Taxol)	6.0 mg/ml (6,000 ppm)	> 240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000 ppm)	> 240
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Cisplatin	1.0 mg/ml (1,000 ppm)	> 240
Carboplatin	10.0 mg/ml (10,000 ppm)	> 240
Docetaxel	10.0 mg/ml (10,000 ppm)	> 240
Ifosfamide	50.0 mg/ml (50,000 ppm)	> 240
Irinotecan	20.0 mg/ml (20,000 ppm)	> 240
Mechlorethamine HCL	1.0 mg/ml (1,000 ppm)	> 240
Methotrexate	25.0 mg/ml (25,000 ppm)	> 240
Mitomycin C	0.5 mg/ml (500 ppm)	> 240
Mitoxantrone	2.0 mg/ml (2,000 ppm)	> 240
Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	> 240

*Please note that the following drugs have low permeation times:
Carmustine (BCNU): 45 minutes and Thiotepa: 30 minutes

5. Predicate Device Identification

510(k) Number: K141982
Product Name: Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs
Manufacturer: WRP Asia Pacific Sdn Bhd.

6. Device Description

The proposed device, 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.
The proposed device is a Powder Free Nitrile Patient Examination Glove that is available in multiple sizes
The proposed device is provided non-sterile. The proposed device is made of Nitrile. The proposed device acts as a barrier.
The proposed device was tested according to the following standards: ASTM D6319-10, ASTM D5151-06, ASTM D6124-06, and ASTM D6978-05. These standards are identified in the following section "Non-clinical test conclusion.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all specifications and the proposed device is Substantially Equivalent (SE) to the predicate device. 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.
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.
ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs
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.

8. Substantially Equivalent (SE) Comparison Conclusion

Table 1 General Comparison

Item	Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146)	Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Remark
Product Code	LZA, LZC	LZA, LZC	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indication for use	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.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single-use indication, powder free, device name, glove size and quantity, Nitrile Examination Gloves, Non-Sterile	Single-use indication, powder free, device name, glove size and 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, Carboplatin, Docetaxel, Ifosfamide, Irinotecan, Mechlorethamine HCL, Methotrexate, Mitomycin C, Mitoxantrone, Vincristine Sulfate	Fluorouracil, Etoposide (Toposar), Cyclophosphamid (Cytoxan), Carmustine (BCNU), Thiotepa, Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin, Ifosfamide, Mitoxantrone, Vincristine Sulfate	Analysis 1

Analysis 1:

The proposed and predicate devices both have a tested for use with chemotherapy drugs claim. However, different chemotherapy drugs have been tested for the proposed device and the results meet the specifications of ASTM D6978

Table 2 Device Dimensions Comparison

Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.10					±0.03
	Palm	0.08					±0.03
	Cuff	0.06					±0.03
Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Size: Min. 240 mm Thickness: Finger (0.07-0.10); Palm(0.07-0.09); Cuff (0.06-0.08)						
Remark	Analysis 2						

Analysis 2:

The proposed device has different size specification as compared to the predicate device, but the proposed device meets the specifications of ASTM D6319.

Table 3 Performance Comparison

Item			Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146)	Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Remark
Colorant			Blue	Blue	Same
Physical properties	Before Aging	Tensile Strength	15 Mpa, min	Meet the Requirements of ASTM D 6319	Analysis 3
		Ultimate Elongation	500% min	Meet the Requirements of ASTM D 6319	
	After Aging	Tensile Strength	14 MPa, min	Meet the Requirements of ASTM D 6319	
		Ultimate Elongation	400% min	Meet the Requirements of ASTM D 6319	
	Comply with ASTM D6319			Comply with ASTM D6319 14 MPa. Min/500% min. before aging; 14 MPa. Min./400% min. After aging	Same
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL 1.5	Be free from holes when tested in accordance with ASTM D5151 under AQL 2.5/Inspection Level G-I	Same
Powder Content			Max. 0.32 mg per glove	Meet the requirements of ASTM D6319 Less than 2mg per glove	Same

Analysis 3:

The proposed device has a different Ultimate Elongation after aging as compared to the predicate device, but the proposed device meets the specifications of ASTM D6319.

Table 4 Safety Comparison

Item		Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146)	Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Remark
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	Same
	Sensitization	Under the conditions of the study, not a sensitizer		
Label and Labeling		Meet FDA's Recommendations	Meet FDA's Recommendations	Same

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device, POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs.