Hebei Titans Hongsen Medical Technology Co., LTD.
% Ray Wang
General Manager
Beijing Believe-Med Technology Services Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401 Cn

Re: K181130
Trade/Device Name: Powder Free Blue 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: LZA, LZC
Dated: July 16, 2018
Received: July 20, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Clarence W. Murray Iii III -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181130

Device Name
Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
The Powder Free Blue 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 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
Bleomycin	15 mg/ml (15,000 ppm)	>240
Busulfan	6 mg/ml (6,000 ppm)	>240
Carboplatin	10 mg/ml (10,000ppm)	>240
Carmustine (BCNU)	3.3 mg/ml (3,300ppm)	8.5 (12.7, 13.4, 8.5)
Cisplatin	1.0 mg/ml (1,000ppm)	>240
Cyclophosphamide(Cytoxan)	20.0 mg/ml (20,000ppm)	>240
Cytarabine	100 mg/ml (100,000ppm)	>240
Cytovene	10 mg/ml (10,000ppm)	>240
Dacarbazine(DTIC)	10.0 mg/ml (10,000ppm)	>240
Daunorubicin	5 mg/ml (5,000ppm)	>240
Docetaxel	10.0 mg/ml(10,000ppm)	>240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000ppm)	>240
Ellence	2 mg/ml (2,000ppm)	>240
Etoposide(Toposar)	20.0 mg/ml(20,000ppm)	>240
Fludarabine	25 mg/ml(25,000ppm)	>240
Fluorouracil	50 mg/ml(50,000ppm)	>240
Gemcitabine (Gemzar)	38 mg/ml(38,000ppm)	>240
Idarubicin	1 mg/ml (1,000ppm)	>240
Ifosfamide	50.0 mg/ml (50,000ppm)	>240
Irinotecan	20.0 mg/ml (20,000ppm)	>240
Mechlorethamine HCI	1.0 mg/ml (1,000ppm)	>240
Melphalan	5 mg/ml (5,000ppm)	>240
Methotrexate	25mg/ml (25,000ppm)	>240
Mitomycin C	0.5 mg/ml (500 ppm)	>240
Mitoxantrone	2.0 mg/ml(2,000ppm)	>240
Oxaliplatin	2.0 mg/ml(2,000ppm)	>240
Paclitaxel (Taxol)	6.0 mg/ml(6,000ppm)	>240
Rituximab	10 mg/ml(10,000ppm)	>240
Thiotepa	10.0 mg/ml (10,000ppm)	36.1 (51.2, 36.1, 45.6)
Trisenox	0.1 mg/ml (100ppm)	>240
Vincristine Sulfate	1.0 mg/ml (1,000ppm)	>240
Vinorelbine	10 mg/ml(10,000ppm)	>240

*Please note that the following drugs have low permeation times:
Carmustine (BCNU): 8.5 minutes and Thiotepa: 36.1 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.

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510(k) Summary

This 510(k) Summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

The assigned 510(k) Number: K181130

1. Date of Preparation: 08/03/2018

2. Sponsor Identification

HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD.
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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 Examination 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 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.
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Vinorelbine	10 mg/ml(10,000ppm)	>240

*Please note that the following drugs have low permeation times:
Carmustine (BCNU): 8.5 minutes and Thiotepa: 36.1 minutes

5. Predicate Device Identification

510(k) Number: K163146
Product Name: POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs
Manufacturer: HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD.

6. Device Description

The proposed device, Powder Free Blue 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 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. Technological Comparison Tables

Table 1 General Comparison

Item	Proposed Device (K181130)	Predicate Device (K163146)	Remark
Product Code	LZA, LZC	LZA, LZC	SAME
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	SAME
Intended use	The Powder Free Blue 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
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	Bleomycin, Busulfan, Carboplatin, Carmustine (BCNU), Cisplatin, Cyclophosphamide(Cytoxan), Cytarabine, Cytovene, Dacarbazine(DTIC) , Daunorubicin, Docetaxel, Doxorubicin, Hydrochloride, Ellence, toposide(Toposar), Fludarabine, Fluorouracil, Gemcitabine (Gemzar), Idarubicin, Ifosfamide, Irinotecan, Mechlorethamine HCI, Melphalan, Methotrexate, Mitomycin C, Mitoxantrone, Oxaliplatin, Paclitaxel (Taxol), Rituximab, Thiotepa, Trisenox, Vincristine Sulfate, Vinorelbine	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	Different

Table 2 Device Dimensions Comparison

Proposed Device (K181130)	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	0.07					±0.02
	Palm	0.05					min
	Cuff	0.05					±0.02
Predicate Device (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
Remark	Different						

Table 3 Performance Comparison

Item			Proposed Device (K181130)	Predicate Device (K163146)	Remark
Colorant			Blue	Blue	Similar
Physical properties	Before Aging	Tensile Strength	15 Mpa, min	15 Mpa, min	SAME
		Ultimate Elongation	500% min	500% min	
	After Aging	Tensile Strength	14 MPa, min	14 MPa, min	

		Ultimate Elongation	400% min	400% min	
	Comply with ASTM D6319			Comply with ASTM D6319	SAME
Detection of Holes			Not detected, in accordance with ASTM D5151	Not detected, in accordance with ASTM D5151	SAME
Powder Content			Max. 0.35 mg per glove	Max. 0.32 mg per glove	Different

Table 4 Safety Comparison

Item		Proposed Device (K181130)	Predicate Device (k163146)	Remark
Material		Nitrile	Nitrile	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Similar
	Sensitization	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	
	In Vitro Cytotoxicity	Under the conditions of the study, not cytotoxic	/	

Different Analysis:

1. The proposed device has different chemotherapy drug permeation claim to the predicate device.
The chemotherapy drug permeation results for the proposed device meets the specifications of ASTM D6978 except for Carmustine and Thiotepa.
2. The proposed device has different thickness specification to the predicate device, but all thickness of proposed devices meets the specifications of ASTM D 6319.
3. The proposed device has different powder content to the predicate device, but all powder content of proposed devices meets the specifications of ASTM D 6319.

8. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all specifications. 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.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Comparison Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.