**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

Hebei Titans Medical Supply Technology Group.,ltd.
% Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd., Li Yuan, Tongzhou District
Beijing, BeiJing 101121 CN

Re: K163553
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 27, 2017
Received: May 1, 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,

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)*
K163553

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue

Indications for Use *(Describe)*
The powder free nitrile patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

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

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K163553

1. Date of Preparation: 2017/05/16

2. Sponsor

HEBEI TITANS MEDICAL SUPPLY TECHNOLOGY GROUP CO., LTD.
EAST OF JINGQIANG COMMUNITY, DAQING STREET, NANGONG, XINGTAI, HEBEI PROVINCE, CHINA

Contact Person: Mr. ShaoZhang Nan
Tel: +86-0319-7295820
Fax: +86-0319-7295801
Email: nanshaozhang@163.com

3. Submission Correspondent

Mr. Ray Wang
Beijing Believe Tech. Service Co., Ltd.
Email: Ray.Wang@believe-med.com

4. Proposed Device Identification

Trade Name: Powder Free Nitrile Patient Examination Gloves, Blue
Device Name: NITRILE Patient Examination Gloves (Powder Free)
Common Name: Patient Examination Gloves

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

Indication for Use Statement:
The powder free nitrile patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: K131440
Product Name: Powder free Patient Examination Gloves, Blue Color
Manufacturer: Hebei HongSen Plastics Technology Co., Ltd.

6. Device Description

The proposed device, Powder Free Nitrile Patient Examination Gloves 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 Powder Free Nitrile Patient Examination Gloves, and includes variations of different size and color. The colors of proposed device is Blue.

The proposed device is not provided as sterilized
The proposed device is made of Nitrile.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as compared to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D6319-10 (Reapproved 2015), Standard Specification for Nitrile Examination Gloves for Medical Application.
ASTM D 5151-06 (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.

## 8. Substantially Equivalent Comparison Conclusion

Table III-1 General Comparison

| ITEM | Proposed Device<br>Powder Free Nitrile Patient Examination Gloves, Blue | Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color | Remark |
|---|---|---|---|
| Product Code | LZA | LZA | Same |
| Regulation No. | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |
| Class | I | I | Same |
| Indication for Use | The powder free nitrile patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. | The Titan powder free nitrile patient examination glove, blue color, is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. It has blue color and is sold as non-sterile. | Same |
| Powdered or Powered free | Powdered free | Powdered free | Same |
| Design Feature | ambidextrous, smooth | ambidextrous, smooth | 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 |

Table III-2 Device Dimensions Comparison

| Proposed Device<br>Powder Free Nitrile Patient Examination Gloves, Blue | 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 (k131440)<br>Powder free Patient Examination Gloves, Blue Color | Designation | Size | | | | | | Tolerance |
| | | XS | S | M | L | XL | XXL | |
| Remark | Different 1 | | | | | | | |

Different 1 analysis:

The proposed device has different size specification to the predicate device, and all specific size specifications for the predicate are not available for comparison, but the predicate and proposed device both meet the specifications of ASTM D 6319.

Table III-3 Performance Comparison

| ITEM | | | Proposed Device Powder Free Nitrile Patient Examination Gloves, Blue | Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color | Remark |
|---|---|---|---|---|---|
| Colorant | | | Blue | Blue | Same |
| Physical Properties | Before Aging | Tensile Strength | 15 MPa, | Comply with ASTM D6319 | Same |
| | | Ultimate Elongation | 500 % min | Comply with ASTM D6319 | Same |
| | After Aging | Tensile Strength | 14 MPa | Comply with ASTM D6319 | Same |
| | | Ultimate Elongation | 400 % min | Comply with ASTM D6319 | Same |
| | Comply with ASTM D6319 | | | Comply with ASTM D6319 | Same |
| Freedom from Holes | | | Be free from holes when tested in accordance with ASTM D5151 | Be free from holes when tested in accordance with ASTM D5151 | Same |
| Powder Content | | | Max. 0.32 mg per glove | Meet the requirements of ASTM 6319 | Same |

Table III-4Safety Comparison

| ITEM | | Proposed Device Powder Free Nitrile Patient Examination Gloves, Blue | Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color | Remark |
|---|---|---|---|---|
| Material | | Nitrile | Nitrile | Same |
| Biocompatibility | Irritation | Under the conditions of the study, not an irritant | Comply with ISO 10993-10 | Same |
| | Sensitization | Under conditions of the study, not a sensitizer. | | |
| Label and Labeling | | Meets recommendations as outlined in the Glove Guidance Manual. | Meets recommendations as outlined in the Glove Guidance Manual. | Same |

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.