Tel 331-215-9065 650 WARRENVILLE RD STE 120 www.1st-pinnacle.com
Fax 331-215-9077 LILSE IL 60532 ktaylor@1st-pinnacke.com

BOX Packaging

Packaging

100 Gloves per Box (XS-XL)
10 Boxes per Master Carton

Tel 331-215-9065
Fax 331-215-9077
650 WARRENVILLE RD STE 120
LILSE IL 60532
www.1st-pinnacle.com
ktaylor@1st-pinnacke.com

Synguard Nitrile Exam Gloves

- No latex protein to cause allergy
- Excellent softness and wearing fitness
- Undifferentated shelf life as normal gloves
- Well suitable for high cleanliness industry like electronic, food service, etc

Tel 331-215-9065
Fax 331-215-9077
650 WARRENVILLE RD STE 120
LILSE IL 60532
www.1st-pinnacle.com
ktaylor@1st-pinnacke.com

SPECIFICATION

SKU	Size	Color	Package	Quality Standards
NGPF7000	XS	Blue White Violet	100pcs/box, 10boxes/ctn	Complies with EN455 and EN374 Complies with ASTM D6319 Complies with ASTM F1671 FDA(510K) available Approved to use with chemotherapy drugs
NGPF7001	S		100pcs/box, 10boxes/ctn	
NGPF7002	M		100pcs/box, 10boxes/ctn	
NGPF7003	L		100pcs/box, 10boxes/ctn	
NGPF7004	XL		100pcs/box, 10boxes/ctn	
NGPF7005	XXL		100pcs/box, 10boxes/ctn	

Tel 331-215-9065
Fax 331-215-9077
650 WARRENVILLE RD STE 120
LILSE IL 60532
www.1st-pinnacle.com
ktaylor@1st-pinnacke.com

OCT 16 2012

510 (K) SUMMARY

K121992

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification:**

Xinwei (Shandong) Plastic and Rubber Products Co., Ltd.
No. 41 Shuangshan Road
Boshan District, Zibo, Shandong
China

Contact Person: Liu, Frank
Tel: 909-548-4828
Fax: 909-548-4807
Email: Johnzhao@basicmedical.com

Date summary prepared: Oct 1, 2012

2. **Name of the Device:**

Xinwei (Shandong) Plastic and Rubber Products Co., Ltd.
Patient Nitrile Examination Gloves, Powder Free, Non-Sterile, Blue Color

3. **Predicate Device Information:**

Tangshan Zhonghong Pulin Group Co., Ltd.
Synthetic Nitrile Patient Examination Gloves – Powder Free (K082598)

4. **Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Nitrile Patient Examination Glove, 80LZA; and meets all requirement of ASTM Standard D6319-10.

5. **Intended Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)

6. **Comparison to Predicate Devices:**

Xinwei (Shandong) Plastic and Rubber Products Co., Ltd. Patient Nitrile Examination Gloves, Powder-Free, Non-Sterile, Blue color are substantially equivalent in safety and effectiveness to the Tangshan Zhonghong Pulin Group Co., Ltd. Powder –Free Nitrile Patient Examination Gloves.

7. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Xinwei (Shandong) Plastic and Rubber Products Co., Ltd. glove production are based on ASTM-D-6319-10. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AOL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AOL 2.5, Inspection Level I, meeting these requirements, Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

8. **Discussion of Clinical Tests Performed:**

Not Applicable – There is no hypoallergenic claim.

9. **Conclusions:**

Xinwei (Shandong) Plastic and Rubber Products Co., Ltd. Patient Nitrile Patient Examination Gloves, Powder-Free, Non-Sterile, Blue color, conform fully to ASTM-D-6319-10 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device	Predicate Device (K082598)
Description	Xinwei (Shandong) Plastic and Rubber Products Co., Ltd. Synthetic, Powder-Free Nitrile Examination Gloves, Blue color	Tangshan Zhonghong Pulin Group Co., Ltd. Powder Free Nitrile Patient Examination Gloves
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Substantially equivalent
Basic Design	A garment covering the hand and waist area. Clovers have separate sheaths or openings for each finger and the thumb.	Substantially equivalent
Materials Used	Nitrile Latex (NBR) Sulfur Accelerator, ZDBC	Same
Single Use	Yes	Yes
Size	S,M,L,XL	Information Unavailable
Sterile	Not sterile	Not sterile
Dimension	Meets ASTM D6319-10	Meets ASTM D6319-10
Physical Property	Meets ASTM D6319-10	Meets ASTM D6319-10
Free of Pinhole	Meets ASTM D5151-06	Meets ASTM D5151-06
Residue Powder	Meets ASTM D6124-06	Meets ASTM D6124-06
Primary Skin Irritation	ISO 10993-10 passes	ISO 10993-10 passes
-Dermal Sensitization	ISO 10993-10 passes	ISO 10993-10 passes
Tensile Strength	>14 MPa	>14 MPa
Ultimate elongation before aging	>500	>500
Ultimate elongation after aging	>500	>500

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 16 2012

Xinwei (Shandong) Plastic and Rubber Products Company, Limited
C/O Basic Medical Industries, Incorporated
Mr. Frank Liu
President
12390 East End Avenue
Chino, California 91710

Re: K121992
Trade/Device Name: Patient Nitrile Examination Gloves, Powder-Free, Non-Sterile, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: August 24, 2012
Received: August 28, 2012

Dear Mr. Liu:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Xinwei (Shandong) Plastic and Rubber Products Co., Ltd.
No. 41 Shuangshan Road, Boshan District, Zibo, Shandong, China
Tel: 0086-15552664010

INDICATIONS FOR USE

Applicant: Xinwei (Shandong) Plastic and Rubber Products Co., Ltd.

510(k) Number: K121992

Device Name: Patient Nitrile Examination Gloves, Powder free, Non-Sterile, Blue Color

Indications of Use:

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)

Prescription Use _____ Over the Counter Use ___X___

Factory Initials _____

Elizabeth D. Claverie-Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K 121992

July 22, 2019

Anhui Intco Medical Products Co. Ltd
% Derek Tian
Official Correspondent
Intco Medical Industries, Inc.
805 Barrington Ave
Ontario, California 91764

Re: K191092
Trade/Device Name: Powder-Free Vinyl Patient Examination Gloves, Yellow Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: April 16, 2019
Received: April 24, 2019

Dear Derek Tian:

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.