DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 3, 2014

Huikang Glove Company, Ltd.
C/O Mr. Chu Xiaoan
Beijing Easy-Link Company
Room 1606, Bldg. 1 Jianxiang Yuan # 209
Bei Si Huan Zhong Road, Haidian District
Beijing 100083
CHINA

Re: K141287
Trade/Device Name: Nitrile Powder Free Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examnation Glove
Regulatory Class: I
Product Code: LZA
Dated: October 28, 2014
Received: October 30, 2014

Dear Mr. Xiaoan:

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 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)*
K141287

Device Name
Nitrile Powder Free Patient Examination Gloves, Blue Color

Indications for Use *(Describe)*
Nitrile Powder Free Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger 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.

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Section 6 510(k) Summary

510(K) Summary

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

"The assigned 510(k) number is: K141287 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Huikang Glove Co., Ltd.
Submitter's address :	Wudaizhuang, Pachigang Town, Luannan County, Hebei Province, 063502, China
Phone number :	（86）315- 4169201
Fax number :	（86）315-4430333
Name of contact person:	Zhang Liang
Date of preparation :	2014-10-28

2.0 Name of the Device

Device Name:	Nitrile Powder Free Patient Examination Gloves, Blue Color
Proprietary/Trade name:	Nitrile Powder Free Patient Examination Gloves, Blue Color
Common Name:	Exam gloves
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital (80)
Product Code:	LZA

3.0 Predicate device

Device Name:	Nitrile Powder Free Patient Examination Gloves, Blue Color
Company name:	Tangshan Zhonghong Pulin Plastic Co.,Ltd.
510(K) Number:	K120970

4.0 Device Description:

4.1 **How the device functions:**
Nitrile films form a barrier to body fluids and bloodborne Pathogens

4.2 **Scientific concepts that form the basis for the device**
The nitrile rubber is water tight under normal conditions of use. Its tensile properties cause it to conform to the hand, allowing movements necessary for a

medical procedure.

4.3 **Physical and performance characteristics such as design, materials and physical properties:**
Nitrile glove is known to create a barrier to bloodborne pathogens and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The glove is manufactured in accordance with the requirements of ASTM D6319 and ASTM D5151 requirements.

5.0 Device Intended Use (Indication for use):

Nitrile Powder Free Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

The Nitrile Powder Free Patient Examination Gloves, Blue Color, non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 6319-10.	Meets
Physical Properties	ASTM standard D 6319-10.	Meets
Freedom from pinholes	21 CFR 800.20	Meets
Powder Residual	ASTM standard D 6319-10 and D6124-06(Reapproved 2011).	Meets <2mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: Third Edition 2010-08-01.	Passes Not a Primary Skin Irritation
	Dermal sensitization in the guinea pig ISO 10993-10: Third Edition 2010-08-01.	Passes Not a Dermal sensitization

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data:

Nitrile Powder Free Patient Examination Gloves, Blue Color, meet requirements per ASTM D6319-10.per ASTM D6124-06(Reapproved 2011), per 21 CFR 800.20 and ISO 10993-10: Third Edition 2010-08-01.

The performance test data of the non clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9.0 Substantial Equivalence Comparison:

Features & Description	Predicate Device	Subject Device	Result of Comparison
Company	Tangshan Zhonghong Pulin Plastic Co.,Ltd.	Huikang Glove Co., Ltd.	--
510(K) Number	K120970	K141287	
Product name	Nitrile Powder Free Patient Examination Gloves, Blue Color	Nitrile Powder Free Patient Examination Gloves, Blue Color	same
Product Code	LZA	LZA	same
Size	Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	same
Intend for use	Nitrile Powder Free Patient Examination Gloves, Blue Color 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.	Nitrile Powder Free Patient Examination Gloves, Blue Color 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.	Substantially equivalent
Device Description and Specifications	Meets ASTM D6319-10	Meets ASTM D6319-10	Substantially equivalent
Dimensions --Length	Meets ASTM D6319-10 ≥230mm min	230mm min for all sizes	Substantially equivalent
Dimensions -- Width	Meets ASTM D6319-10 Small 70-90 mm Medium 85-105mm Large 100-120mm Xlarge 110-130 mm	Small 83-87 mm Medium 93-97mm Large 104-109mm X large 114-119 mm	Substantially equivalent
Dimensions --Thickness	Meets ASTM D6319-10 Finger 0.05mm min. Palm 0.05mm min.	Thickness (mm) min. Finger 0.10 mm min. Palm 0.06 mm min.	Substantially equivalent
Physical Properties	Meets ASTM D D6319-10 Before aging/after aging Elongation ≥500% Tensile Strength≥ 14MPa	Before aging/after aging Elongation :520-580% Tensile Strength:22-34 MPa	Substantially equivalent
Freedom from Pinholes	Meets • 21 CFR 800.20 • ASTM D6319-10 • ASTM D 5151-06 (Reapproved 2011)	Meets ASTM D5151-06 (Reapproved 2011) Holes at Inspection Level I AQL2.5	Substantially equivalent
Residual Powder	Meets ASTM D 6124-06 (Reapproved 2011) below 2mg of residual powder	Meets ASTM D 6124-06 (Reapproved 2011) Results generated values below 2mg of residual powder	Substantially equivalent

Materials used to fabricate the devices	Nitrile	Nitrile	Substantially equivalent
Dusting or Donning Powder:	PU	PU	Substantially equivalent
Dusting or Donning Powder: name	PU	Surface Coating Agent	Substantially equivalent
Compare performance data supporting substantial equivalence	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	Substantially equivalent
Single Patient Use	Single Patient Use	Single Patient Use	Substantially equivalent
Biocompatibility	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1:2006	Under the conditions of the study, not an irritant and under conditions of the study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10: Third Edition 2010-08-01.	Substantially equivalent
Labeling for the legally marketed device to which substantial equivalence is claimed.	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile	Substantially equivalent

10.0 Substantial Equivalence Comparison:

It can be concluded that the Nitrile Powder Free Patient Examination Gloves, Blue Color meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims.

It can be concluded that the Nitrile Powder Free Patient Examination Gloves, Blue Color is as safe, as effective, and performs as well as the predicate device, Nitrile Powder Free Patient Examination Gloves, Blue Color, Tangshan Zhonghong Pulin Plastic Co.,Ltd.. K120970.