DEC - 9 2013

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: K131823 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Dong Tai City Huayi Gloves Co., Ltd.
Submitter's address :	No.68 Jingyi Road, ChengDong New District, DongTai, Jiangsu, 224200, China
Phone number :	0086-515-85332088
Fax number :	0086-515-85332688
Name of contact person:	Ms.Zhu Ya Fen
Date of preparation :	2013-10-07

2.0 Name of the Device

Device Name:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Proprietary/Trade name:	DongTai
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:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Company name:	Jiangsu Dongling Plastic & Rubber Co., Ltd.
510(K) Number:	K110247

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. It's 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 leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the requirements of ASTM D6319 and ASTM D5151 requirements.

5.0 Device Intended Use (Indication for use):

Powder Free Nitrile 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 Powder Free Nitrile 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 10993-10:2002 /Amd.1:2006	Passes Not a Primary Skin Irritant
	Dermal sensitization in the guinea pig ISO 10993-10: 2002 /Amd.1:2006	Passes Not a Dermal Sensitizer

7.0 Substantial Equivalent Based on Assessment ofNon-ClinicalPerformance Data:

Powder Free Nitrile 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: 2002/Amd.1:2006.

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	Medical Glove Guidance Manual	Subject Device	Result of Comparison
Company	Jiangsu Dongling Plastic & Rubber Co., Ltd.		Dong Tai City Huayi Gloves Co., Ltd.	--
510(K) Number	K110247		K131823	
Product name	Powder Free Nitrile Patient Examination Gloves, Blue Color		Powder Free Nitrile Patient Examination Gloves, Blue Color	same
Product Code	LZA	LZA	LZA	same
Size	Small/ Medium/ Large/X large		Small/ Medium/ Large/X large	same
Intend for use	Powder Free Nitrile 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.	Powder Free Examination Gloves: A powder-free patient examination glove 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.	Powder Free Nitrile 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	If nitrile gloves: Does the above data for your nitrile examination glove meet all the current specifications listed under the applicable ASTM standard D6319 or an equivalent consensus standard?	Meets ASTM D6319-10	Substantially equivalent
Dimensions --Length	Meets ASTM D6319-10 ≥230mm min	ASTM D6319	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	ASTM D6319	 Small 82-86 mm Medium 94-98mm Large 107-113mm X large 115-121 mm	Substantially equivalent
Dimensions --Thickness	Meets ASTM D6319-10 Finger 0.05mm min. Palm 0.05mm min.		 Thickness (mm) min. Finger 0.09-0.13 Palm 0.09-0.13	Substantially equivalent
Physical Properties	Meets ASTM D D6319-10 Before aging/after aging Elongation ≥500% Tensile Strength≥ 14MPa	ASTM D6319	 Before aging/after aging Elongation :540-600% Tensile Strength:19-23 MPa	Substantially equivalent
Freedom from Pinholes	Meets • 21 CFR 800.20 • ASTM D6319-10 • ASTM D 5151-06 (Reapproved 2011)	21 CFR 800.20 ASTM D5250 ASTM D 5151	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	ASTM D 6124	Meets ASTM D 6124-06 (Reapproved 2011) Results generated values below 2mg of residual powder	Substantially equivalent
Materials used to fabricate the devices	Nitrile	If the glove is made of a polymer or other type of material. identify the material.	Nitrile	Substantially equivalent
Dusting or Donning Powder:	PU	If a donning lubricant is used, state the composition and include biocompatibility data for the lubricant in an identified attachment; also state the name, manufacturer, and address below	PU-120C	Substantially equivalent
Dusting or Donning Powder: name	PU	Lubricant Generic Name/ Lubricant Brand Name	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)	At this time FDA recognizes the following standards: Patient Examination Gloves(PVC)ASTM D5151(Detection of Holes in Medical Gloves)ASTM D6124(Residual Powder on Medical Gloves)ASTM	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	Substantially equivalent

		D6319 (Nitrile Gloves)		
Single Patient Use	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	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES ISO 10993-10	The test article was a non-irritant and non-sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002 /Amd.1:2006	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	Chapter 4	-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 Powder Free Nitrile 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 Powder Free Nitrile Patient Examination Gloves, Blue Color is as safe, as effective, and performs as well as the predicate device, Powder Free Nitrile Patient Examination Gloves, Blue Color, Jiangsu Dongling Plastic & Rubber Co., Ltd. K110247

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

December 9, 2013

Dong Tai City Huayi Gloves Company, Limited
C/O Mr. Chu Xiaoan
Official Correspondent
Beijing Easy-Link Co.
Room 1606 Bldg. 1 Jianxiang Yuan #209
Bei Si Huan Zhong Road, Haidian District
Beijing 100083
CHINA

Re: K131823
Trade/Device Name: Powder-Free Nitrile Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: October 7, 2013
Received: October 24, 2013

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,

Erin I. Keith, M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(If known)*
K131823

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue Color

Indications for Use *(Describe)*

Powder Free Nitrile 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S
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