Section C (rev.02)510(k) Summary (21 CFR 807.92)

510(K) Summary

JUN 10 2011

"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: K110248

Premarket Notification [510(k)] Summary

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Name of contact person:	Mr.ZhiJun Xu
Date the summary was prepared:	Dec.24, 2010

Device Name:	Powder Free Nitrile Patient Examination Gloves,White Color
Proprietary/Trade name:	Powder Free Nitrile Patient Examination Gloves,White Color Other clients private labeling
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

Class I* Powder Free Nitrile Patient Examination Gloves,White Color that meets all of the requirements of ASTM D 6319 00a(2005)e1.

Predicate device: POWDER FREE BLUE NITRILE PATIENT EXAMINATION GLOVE TANGSHAN ZHONGHONG PULIN GROUP CO., LTD. K082598.

Device Description: Powder Free Nitrile Patient Examination Gloves,White Color are disposable device which made of nitrile synthetic rubber , intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner and they meets all of the requirements of ASTM standard D 6319 00a (2005)e1.

Device Intended Use (indication for use): Powder Free Nitrile Patient Examination Gloves,White 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.

A summary of the technological characteristics of new device compared to the predicate device.

The Powder Free Nitrile Patient Examination Gloves,White 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 00a (2005)e1.	Meets
Physical Properties	ASTM standard D 6319 00a (2005)e1.	Meets
Freedom from pinholes	21 CFR 800.20	Meets
Powder Residual	ASTM standard D 6319 00a (2005)e1. and D6124-06	Meets <2mg/glove
Biocompatability	Primary Skin Irritation in rabbits ISO 10993-10	Passes Not a Primary Skin Irritation
	Dermal sensitization in the guinea pig ISO 10993-10	Passes Not a Dermal sensitization

A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Powder Free Nitrile Patient Examination Gloves,White Color, meet requirements per ASTM D6319 00a (2005)e1, per ASTM D6124-06, 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.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

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

Conclusions

It can be concluded that the Powder Free Nitrile Patient Examination Gloves,White 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,White Color is as safe, as effective, and performs as well as the predicate device, POWDER FREE BLUE NITRILE PATIENT EXAMINATION GLOVE, TANGSHAN ZHONGHONG PULIN GROUP CO., LTD.. K082598

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUN 10 2011

Re: K110248
Trade/Device Name: Powder-Free Nitrile Patient Examination Glove, White Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examnation Glove
Regulatory Class: I
Product Code: LZA
Dated: May 26, 2011
Received: May 26, 2011

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 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

Section B Indications for Use

INDICATIONS FOR USE

Applicant: JiangSu DongLing Plastic & Rubber Co.,Ltd

510(k) Number (if known): * K110248

Device Name: Powder Free Nitrile Patient Examination Gloves,White Color

Indications For Use:

Powder Free Nitrile Patient Examination Gloves,White 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.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wilson

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

510(k) Number: K110248