Appendix III. 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 9807.92.

The Assigned 510(k) Number is: _____

FEB 26

1. Applicant Device Information

Trade/Proprietary Name:
Latex Examination Gloves (Powdered and Powder-Free)
Nitrile Examination Gloves (Powdered and Powder-Free)
Common Name:
Latex Examination Gloves (pre-powdered and powder free)
Nitrile Examination Gloves (pre-powdered and powder free)
Classification Name:
Glove, patient examination, latex
Glove, patient examination, poly
Device Class: I
Product Code: LYY & LZA
Regulation Number:
880.6250
Intended Use:
A 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.

2. Submitter Information

Manufacturer Name:
Zhanjiang Jiali Glove Products Co., LTD
YinHao Village, MaZhi Road
Zhanjiang, Guangdong, 524002, China

Contact Person of the Submission:
Ms. Diana Hong
Mr. Eric Chen
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhong Shan Nan Er Road
Shanghai, China 20020

Phone: +86-21-64264467 x 152
Fax: +86-21-64264468 x 809
Email: Diana.hong@mid-link.net

3. Predicate Device

1). CHLORINATED, POLYMER-COATED POWDER-FREE LATEX EXAMINATION GLOVE WITH EXTRACTABLE PROTEIN CONTENT LABELING CLAIM
K Number: K062965
Product Code: LYY
Intended Use:
A 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.
Manufactured by
KOSSAN LATEX INDUSTRIES (M) SDN. BHD.
2530 Riva Road, suite 308
Annapolis, MD 21401
2). LATEX POWDERED EXAMINATION GLOVE
K Number: K060858
Product Code: LYY
Intended Use:
A 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.
Manufactured by
HIGH MOMENTUM SDN BHD

3). NITRILE POWDER FREE EXAMINATION GLOVES (GREEN)
K Number: K063046
Product Code: LZA
Intended Use:
The nitrile examination gloves is a disposable device intended for medical and dental purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.
Manufactured by
Hartalega SDN BHD

4). POWDER NITRILE EXAMINATION GLOVE
K Number: K063522

Product Code: LZA

Intended Use:

The nitrile examination gloves is a disposable device intended for medical and dental purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Manufactured by

HL RUBBER INDUSTRIES SDN BHD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2008

Zhanjiang Jiali Glove Products Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, Zhongxin Zhongshan Mansion
No. 19, Lane 999, Zhong Shan, No. 2 Road(S)
Shanghai, 200030
CHINA

Re: K072145
Trade/Device Name: Latex Examination Gloves (Powdered and Powder-Free)
Nitrile Examination Gloves (Powdered and Powder-Free)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY, LZA
Dated: February 19, 2008
Received: February 19, 2008

Dear Ms. Hong:

This letter corrects our substantially equivalent letter of February 19, 2008.

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 (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.

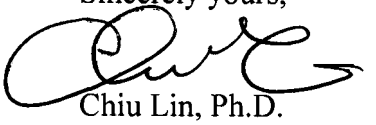
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix V. Indications for Use

510(k) Number: K072145

Device Name: Latex Examination Gloves (Powdered and Powder-Free)
Nitrile Examination Gloves (Powdered and Powder-Free)

Indications for Use:

A patient examination glove is disposable devices intended for medical purpose that is worn on the hand or finger(s) to prevent contamination between patient and examiner.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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

510(k) Number: K072145