K101645/52



# 510(k) SUMMARY

AUG 26 2010

**NON-CHLORINATED, POLYMER COATED, POWDER FREE NATURAL RUBBER LATEX EXAMINATION GLOVES AND PROTEIN LABELING CLAIM OF 50 MICROGRAMS OR LESS PROTEIN**

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| Submitter's Name | LATEXX MANUFACTURING SDN. BHD. |
| Submitter's Address | PT 5054, Kamunting Industrial Estate<br>34600 Taiping, Perak,<br>Malaysia |
| Submitter's Phone Number | 605-891 1111 / 605-829 5590 |
| Submitter's Fax Number | 605-829 5590 |
| Name of Contact Person | Terence Lim Sin Kooi |
| Date of Preparation | 27 May 2010 |
| Name of Device | |
| Trade Name : | NON-CHLORINATED, POLYMER COATED, POWDER FREE NATURAL RUBBER LATEX EXAMINATION GLOVES AND PROTEIN LABELING CLAIM OF 50 MICROGRAMS OR LESS PROTEIN |
| Common Name : | Latex Examination Gloves |
| Classification Name : | Patient Examination Gloves |

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| Legally Marketed Device to which Equivalency is Being Claimed | Non-Chlorinated, Polymer Coated, Powder Free Natural Rubber Latex Examination Gloves and Protein Labeling Claim of 50 Micrograms or Less Protein as described in this 510 K Notification is substantially equivalent to the current Class 1 Patient Examination Glove bearing the product code 80LYY ( 21 CFR 880.6250 ). It meets all the current specifications listed under the ASTM Specification D 3578-05$^{\varepsilon 1}$, Standard Specification for Rubber Examination Gloves. |
| Description of the Device | Non-Chlorinated, Polymer Coated, Powder Free Natural Rubber Latex Examination Glove and Protein Labeling Claim of 50 Micrograms or Less Protein is substantially equivalent to the Class 1 patient examination glove bearing the product code 80LYY ( 21 CFR 880.6250 ). It meets all the current specifications listed under the ASTM Specification D-3578-05$^{\varepsilon 1}$, Standard Specification for Rubber Examination Gloves. They are made from natural rubber latex. They are natural white in color and are powder free. |
| Intended Use of the Device | Non-Chlorinated, Polymer Coated, Powder Free Natural Rubber Latex Examination Gloves and Protein Labeling Claim of 50 Micrograms or Less Protein are intended for single use for medical purposes that is worn on the hand of health care and similar personnel to prevent contamination between the health care personnel and the patients. |
| Summary of Technological Characteristic Compared to the Predicate Device | There is no different technological characteristic. Gloves are made from natural rubber latex compound and the initial products are low powdered natural rubber latex gloves. These gloves are using the existing technology, i.e. multiple washing and rinsing processes. |
| Brief Description of Non-Clinical Tests | Testing were performed per ASTM D 3578-05$^{\varepsilon 1}$, Standard Specification for Rubber Examination Gloves and 21 CFR 800.20. Gloves meet all the current ASTM D 3578-05$^{\varepsilon 1}$ requirements.<br>Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization.<br>Final product has been tested negative for the presence of starch using the USP iodine test. |

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| Brief description of Clinical Tests | No new clinical tests were conducted under this 510(k). |
| Conclusions Drawn from the Non-Clinical and Clinical Tests | Non-Clinical laboratory and animal based test data indicate that the powder free product meets all performance and biocompatibility requirements. |
| Other Information Deemed Necessary by FDA | Not Applicable. |

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

Mr. Terence Lim Sin Kooi
Quality Assurance and Regulatory Affairs
Latexx Manufacturing Sdn. Bhd.
PT 5054 Kamunting Industrial Estate
Taiping, Perak
MALAYSIA 34600

AUG 26 2010

Re: K101645
Trade/Device Name: Non-Chorinated, Polymer Coated, Powder Free Natural Rubber Latex Examination Glove and Protein Labeling Claim of 50 Microgram or Less Protein
Regulation Number: CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 17, 2010
Received: August 19, 2010

Dear Mr. Kim Sin Kooi:

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,

for Susan Runner

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

K101645/S2

Non-Chlorinated Polymer Coated Powder Free
Natural Rubber Latex Examination Gloves And
Protein Labeling Claim of 50 Micrograms or Less Protein

Attachment 2

# INDICATIONS FOR USE

Applicant : **LATEXX MANUFACTURING SDN. BHD.**
**PT 5054, Kamunting Industrial Estate,**
**34600 Kamunting , Perak,**
**Malaysia.**

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

Device Name : **NON-CHORINATED, POLYMER COATED, POWDER FREE NATURAL RUBBER LATEX EXAMINATION GLOVE AND PROTEIN LABELING CLAIM OF 50 MICROGRAM OR LESS PROTEIN**

Indications For Use :

***Non-Chlorinated, Polymer Coated, Powder Free Natural Rubber Latex Examination Glove and Protein Labeling Claim of 50 Micrograms or Les Protein is a single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient.***

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Concurrence of CDRH Office of Device Evaluation (ODE )

Prescription Use_____ OR Over-The-Counter_____X_____
Per 21 CFR 801.109

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

510(k) Number: K101645