PT. WRP Buana Multicorpora

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SEP 16 2002

K022343

510 (K) SUMMARY OF POWDER FREE LATEX EXAMINATION GLOVES, NON STERILE (Protein Content Labeling Claim 50μg/g or less)

1. Trade Name : Glovetex Powder Free Latex Examination Gloves, Non Sterile (Protein Content Labeling Claim 50 μg/g or less).

2. Device Name : Powder Free Latex Examination Gloves, Non Sterile (Protein Content Labeling Claim 50 μg/g or less).

3. Device Listing No. : A 907707

4. Description of the Device :

   Powder Free Latex Examination Gloves, Non Sterile (Protein Content Labeling Claim 50 μg/g or less) is Class I Device, Code No. 80LYY. These gloves are made of natural rubber latex. Based on the protein content test result obtained the gloves are well bellow 50 μg/g and support our protein content labeling claim.

   The result of the performance testing of Powder Free Latex Examination Gloves, Non Sterile (Protein Content Labeling Claim 50μg/g or less) are detailed in this submission and are summarized as in the attachment-1.

5. Equivalency :

   Powder Free Latex Examination Gloves, Non Sterile (Protein Content Labeling Claim 50 μg/g or less) are substantially equivalent to Powder Free Latex Examination Gloves, Non-Sterile submitted and cleared under 510(k) number K970115. The only difference in this submission is to include the protein content labeling claim 50μg/g or less with no changes in product design.

6. Intended Use :
   These gloves are intended to be worn on examiner's hand or finger to prevent contamination between patient and examiner.

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Comparison with a Predicate Devices

Characteristics	**Powder Free Latex Examination Gloves, Non Sterile.**	**Powder Free Latex Examination Gloves, Non Sterile with Protein Content labeling Claim**
Product Code	80LYY	80LYY
510 (K) Number	K970115	-
Comply with ASTM D 3578	Meets	Meets
Materials	Natural Rubber Latex	Natural Rubber Latex
Intended Use	To be worn on the examiner's hand or finger to prevent contamination between patient and examiner	To be worn on the examiner's hand or finger to prevent contamination between patient and examiner
Comply with FDA 1000ml Water Leak Test	Meets	Meets
Protein Content labeling Claim (50μg/g or less)	N/A	Meets

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2002

Mr. Ng Poy Sin
President Director
PT. WRP Buana Multicorpora
Jalan Jermal
No. 20-B, Kelurahan, Sei Mati
Medan-Labuhan Km 17,
INDONESIA

Re: K022343
Trade/Device Name: Glovetex Powder Free Latex Examination Gloves, Non-Sterile Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: August 26, 2002
Received: August 30,2002

Dear Mr. Sin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

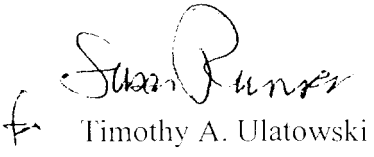
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 begin 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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INDICATIONS FOR USE

Applicant : PT. WRP Buana Multicorpora

510(k) Number (if known) : K022343

Device Name : POWDER FREE LATEX EXAMINATION GLOVES NON STERILE (Protein Content labeling Claim 50 µg/g or less) Contains 50 mcgm or less of Total Water extractable Protein per Gram

Indications For Use:

The Powder Free Latex Examination Gloves, Non-Sterile (Protein Content Labeling 50 µg/g or less) is a disposable device and made of Natural Rubber Latex intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

_____ _____ _____ _____ _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)

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

510(k) Number: K022343