Attachment 17

K070821

MAY 10 2007

510(k) SUMMARY

POWDERED NATURAL RUBBER LATEX EXAMINATION GLOVES

Submitter's Name	MEDTEXX MANUFACTURING SDN. BHD.
Submitter's Address	PT 4004, Kamunting Industrial Estate 34600 Taiping, Perak, Malaysia
Submitter's Phone Number	605-891 1111 / 605-891 5555
Submitter's Fax Number	605-891 1088
Name of Contact Person	Ooi Loon Seng
Date of Preparation	
Name of Device Trade Name : Common Name : Classification Name :	 POWDERED NATURAL RUBBER LATEX EXAMINATION GLOVES Latex Examination Gloves Patient Examination Gloves
Legally Marketed Device to which Equivalency is Being Claimed	Powdered Natural Rubber Latex Examination Gloves 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, Standard Specification for Rubber Examination Gloves.
Description of the Device	Powdered Natural Rubber Latex Examination Glove 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, Standard Specification for Rubber Examination Gloves. They are made from natural rubber latex. They are natural white in color and are powdered.
Intended Use of the Device	Powdered Natural Rubber Latex Examination Gloves 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 powdered natural rubber latex examination gloves.
Brief Description of Non-Clinical Tests	Testing performed per ASTM D 3578-05, Standard Specification for Rubber Examination Gloves and 21 CFR 800.20. Gloves meet all the current ASTM D 3578-05. Primary skin irritation testing in the rabbit and delayed dermal contact sensitization study in the guinea pigs indicate no irritation or sensitization.
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 test data indicate that the powdered 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
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2007

Mdm. Ooi Loon Seng
Regulatory Affairs Manager
Medtexx Manufacturing Sdn. Bhd.
PT 4004 Kamunting Industrial Estate, Taiping
Kamunting
Perak, 34600 MALAYSIA

Re: K070821
Trade/Device Name: Powdered Natural Rubber Latex Examination Gloves (Protein Label Claim)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: March 23, 2007
Received: March 26, 2006

Dear Mdm. Seng:

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), 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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

INDICATIONS FOR USE

Applicant : **MEDTEXX MANUFACTURING SDN. BHD.**
PT 4004, Kamunting Industrial Estate,
34600 Kamunting , Perak,
Malaysia.

510(k) Number (if known) : K070821 *

Device Name : **POWDERED NATURAL RUBBER LATEX EXAMINATION GLOVES (PROTEIN LABEL CLAIM)**

Indications For Use :

Powdered Natural Rubber Latex Examination Glove is a single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use__________ OR Over-The-Counter X
Per 21 CFR 801.109

(Signature)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...k) Number: K070821