

**MEDTEXX POWDER FREE LATEX EXAMINATION GLOVES**

K991153

<b>Submitter's Name :</b>	Medtexx Industries (Thai) Company Limited.
<b>Submitter's Address :</b>	200 MU4, Tambun Tachaang, Amphur Bangkam, 90110 Songkhla, Thailand.
<b>Submitter's Phone Number</b>	661 230 3606
<b>Submitter's Fax Number :</b>	661 230 3606
<b>Name of Contact Person :</b>	Steven Tan, Cheng Kim
<b>Date of Preparation :</b>	February 22, 1999
<b>Name of Device :</b>	
<b>Trade Name :</b>	MEDTEXX POWDER FREE LATEX EXAMINATION GLOVES
<b>Common Name :</b>	Latex examination gloves
<b>Classification Name :</b>	Patient Examination Gloves
<b>Legally Marketed Device to Which Equivalency is Being Claimed :</b>	MEDTEXX Powder Free Latex Examination Gloves as described in the 510(k) notification are substantially equivalent to the Class 1 patient examination glove 80LYY. It meets all the current specifications listed under the ASTM Specification D 3578 – 95, Standard Specification for Rubber Examination Gloves.
<b>Description of the Device :</b>	MEDTEXX Powder Free Latex Examination Gloves meet the current specifications listed under the ASTM Specification D 3578 95, Standard Specification for Rubber Examination Gloves. They are natural white in color and are powder free.
<b>Intended Use of the Device:</b>	MEDTEXX Powder Free Latex Examination

	Gloves are intended for single use for medical purposes and are worn on the hand of health care and similar personnel to prevent contamination between the health care personnel and the patients.
Summary of Technological Characteristics Compared to the Predicate Device :	There are no different technological characteristics. Gloves are made from natural rubber compound and the initial products are powdered natural latex examination gloves. These gloves are then further processed into powder free gloves using the existing technology, i.e. chlorinating and then washing the surfaces of the gloves.
Brief Discussion of Nonclinical Tests :	Testing is performed as per ASTM D 3578-95 and 21 CFR 800.20. Gloves meet all the current specifications listed under the ASTM Specification D 3578 – 95, Standard Specification for Rubber Examination Gloves.  Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization.  Final product is negative for the test for presence of starch using the USP iodine test.
Brief Discussion of Clinical Tests :	No new clinical tests were conducted under this 510(k).
Conclusions Drawn for the Nonclinical and Clinical Tests :	Nonclinical laboratory and animal data indicate that the powder free product meets all performance and biocompatibility requirements.
Other Information Deemed Necessary by FDA :	Not applicable



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 21 1999

Mr. Stephen Tan Cheng Kim  
General Manager  
MedTexx Industries (Thai) Company Limited  
200 MU-4, Tambol Tachang  
Amphur Bangklam, 90110  
Songkhla, Thailand

Re: K991153  
Trade Name: MedTexx Powder-Free Latex Examination Gloves  
Contains 50 Microgram or Less of Total Water  
Extractable Protein Per Gram  
Regulatory Class: I  
Product Code: LYY  
Dated: May 28, 1999  
Received: June 4, 1999

Dear Mr. Stephen Tan Cheng Kim:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

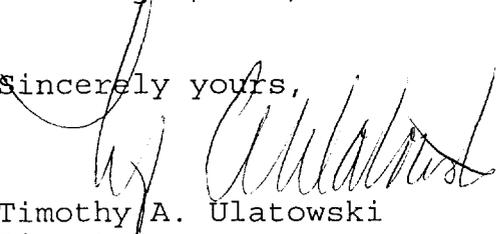
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

# INDICATIONS FOR USE

Applicant : MEDTEXX INDUSTRIES (THAI) COMPANY  
 LTD., MALAYSIA.  
 200 MU4, TAMBUN TACHAANG,  
 AMPHUR BANGKAM, 90110  
 SONGKHLA, THAILAND.

510(k) Number : K991153 \*  
 (if known)

Device Name : MEDTEXX POWDERFREE LATEX EXAMINATION  
 GLOVE (PROTEIN LABEL CLAIM)  
 50 Microgram or less of Total Water Extractable Protein per gram

Indications For Use :

*Medtexx Powder free Latex Examination Glove is a single use device intended 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 patient.*

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Chin S. Lin  
 (Division Sign-Off)  
 Division of Dental, Infection Control,  
 and General Hospital Devices  
 510(k) Number K991153

Prescription Use \_\_\_\_\_ OR Over-The-Counter X