SEP 24 1999 K992671

Attachment 14

510(k) SUMMARY

QTEXX PRE – POWDERED NITRILE EXAMINATION GLOVES

Submitter's Name :	LATEXX PARTNERS BERHAD
Submitter's Address :	PT 5054, Kamunting Industrial Estate, P.O. Box 9 34600 Kamunting, Perak Malaysia
Submitter's Phone Number	605 891 5555
Submitter 's Fax Number :	605 891 2688
Name of Contact Person :	Lim, Chong Eng
Date of Preparation :	September 9, 1999
Name of Device : Trade Name : Common Name Classification Name :	 QTEXX PRE – POWDERED NITRILE EXAMINATION GLOVES Nitrile examination gloves Patient Examination Gloves
Legally Marketed Device to Which Equivalency is Being Claimed :	QTEXX Pre – Powdered Nitrile Examination Gloves as described in the 510(k) notification are substantially equivalent to the Class 1 patient examination glove (Nitrile) 80LZA, that meets the current ASTM D 3578 – 99 Standard Specification for Rubber Examination Gloves for Medical Application.
Description of the Device :	QTEXX Pre – Powdered Nitrile Examination Gloves meet the current specifications listed under the ASTM Specification D 3578 – 99 Standard Specification for Rubber Examination Gloves. They are blue or natural white in colour.

K994671

Attachment 14

Intended Use of the Device:	QTEXX Pre – Powdered Nitrile 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 nitrile rubber compound and the initial products are powdered nitrile examination gloves.
Brief Discussion of Nonclinical Tests :	Testing is performed as per ASTM D 3578 -99 and 21 CFR 800.20. Gloves meet all the current specifications listed under the ASTM Specification D 3578 – 99 Standard Specification for Nitrile 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 pre powdered nitrile product meets all performance and biocompatability 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

SEP 24 1999

Mr. C.E. Lim
General Manger
Latexx Partners Bhd.
PT 5054, Kamunting Industrial Estate
P.O. Box 9, 34600 Kamunting,
Taiping, Perak, Malaysia

Re: K992671
Trade Name: Qtexx Pre-Powdered Nitrile Examination Gloves (Blue)
Regulatory Class: I
Product Code: LZA
Dated: September 9, 1999
Received: September 14, 1999

Dear Mr. Lim:

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. 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) 594-4690. 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

Attachment 2

INDICATIONS FOR USE

Applicant : LATEXX PARTNERS BERHAD,
PT 5054, Kamunting Industrial Estate
P.O. Box 9
34600 Kamunting, Perak
Malaysia

510(k) Number (if known) : _____

Device Name : QTEXX PRE – POWDERED NITRILE EXAMINATION GLOVES (BLUE)

Indications For Use :

QTEXX Pre - Powdered Nitrile 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 K992671

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