K013303

Attachment 17

510(k) SUMMARY JAN 2 3 2002

CLEANTEXX™ POWDER FREE SYNTHETIC RUBBER LATEX EXAMINATION GLOVES

Submitter's Name	LATEXX MANUFACTURING SDN. BHD.
Submitter's Address	PT 5054, Kamunting Industrial Estate P.O. Box 9, 34600 Taiping, Perak Malaysia
Submitter's Phone Number	605 891 1111
Submitter 's Fax Number	605 891 1088
Name of Contact Person	Teoh, Choh Shee
Date of Preparation	August 20, 2001
Name of Device Trade Name : Common Name : Classification Name :	 Cleantexx™ Powder Free Synthetic Rubber Latex (BarrierPro™) Examination Glove Synthetic Rubber Examination Gloves Patient Examination Gloves, Powder-free
Legally Marketed Device to Which Equivalency is Being Claimed	Cleantexx™ Powder Free Synthetic Rubber Latex Examination Glove as described in this 510K Notification is substantially equivalent to the current Class I patient examination glove bearing the product code 80LZA (21CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D 6319–00a, Standard Specification for Nitrile Examination Gloves for Medical Application.
Description of the Device	Cleantexx™ Powder Free Synthetic Rubber Latex Examination Glove meets all the current specifications listed under the ASTM Specification D 6319–00, Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from BarrierPro™ synthetic rubber latex, a polybutadiene based copolymer. They are natural white in color and are powder free.

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Intended Use of the Device	Cleantexx™ Powder Free Synthetic Rubber Latex Examination Glove is 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 Characteristics Compared to the Predicate Device	There is no different technological characteristic. Gloves are made from BarrierPro™ (Trade Mark of Reichhold Chemicals, Inc. of USA) synthetic rubber latex compound and the initial products are low powdered synthetic rubber latex gloves. These gloves are then further processed into powder free gloves using the existing technology, i.e. multiple washing and rinsing processes.
Brief Description of Non-clinical Tests	Testing performed per ASTM D 6319 – 00a, Standard Specification for Nitrile Examination Gloves for Medical Application and 21 CFR 800.20. Gloves meet all the current ASTM D 6319–00a. 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 presence of starch using the USP iodine test.
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
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2002

Mr. Teoh Choh Shee
General Manager
Latexx Manufacturing Sdn. Bhd.
PT. 5054,
Kamunting Industrial Estate
Taiping, Perak,
MALAYSIA

Re: K013303
Trade/Device Name: Cleantexx Powder-Free Synthetic Latex Examination Glove made with "Barrier-Pro" Butadiene Co-Polmer
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: December 11, 2001
Received: December 11, 2001

Dear Mr.Shee:

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,

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 : **LATEXX MANUFACTURING SDN.BHD.**
PT 5054, Kamunting Industrial Estate
P.O. Box 9
34600 Taiping Perak
MALAYSIA

510(k) Number (if known) : K013303 *

Device Name : **Cleantexx Powder-Free Synthetic Latex Examination Glove made with "Barrier-Pro™" Butadiene Co-polymer**

Indications For Use :

Powder Free Synthetic Rubber Latex (BarrierPro™) 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)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K013303

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