

K981159
JUN 1 1998

510(k) SUMMARY

PROFLEX* POWDER FREE NITRILE EXAMINATION GLOVES

Submitter's Name :	Latex Partners Bhd.
Submitter's Address :	PT 5054, Kamunting Industrial Estate 34600 Taiping Perak Malaysia
Submitter's Phone Number	605 891 5555
Submitter's Fax Number :	605 891 2688
Name of Contact Person :	Goh, See Khek
Date of Preparation :	February 25, 1998
Name of Device :	
Trade Name :	PROFLEX* POWDER FREE NITRILE EXAMINATION GLOVES
Common Name :	Nitrile examination gloves
Classification Name :	Patient Examination Gloves
Legally Marketed Device to Which Equivalency is Being Claimed :	PROFLEX* Powder Free 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 draft ASTM Standard Specification for Nitrile Examination Gloves for Medical Application. It also meets all the current specifications listed under the ASTM Specification D 3578 - 95, Standard Specification for Rubber Examination Gloves, EXCEPT for tensile strength and ultimate elongation.

Description of the Device :	PROFLEX* Powder Free Nitrile Examination Gloves meet the current draft ASTM Standard Specification for Nitrile Examination Gloves for Medical Application. It also meets all the current specifications listed under the ASTM Specification D 3578 – 95, Standard Specification for Rubber Examination Gloves, <u>EXCEPT</u> for tensile strength and ultimate elongation requirement. They are blue or natural white in colour and are powder free.
Intended Use of the Device:	PROFLEX* Powder Free Nitrile 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 Characteristics Compared to the Predicate Device :	There is no different technological characteristics. Gloves are made from Nitrile rubber compound and the initial products are powdered Nitrile rubber gloves. These gloves are then further processed into powder free gloves using the existing technology, i.e. washing and then chlorinating the surfaces of the gloves.
Brief Discussion of Nonclinical Tests :	Testing performed per ASTM D 3578-95 (also per current draft ASTM Standard Specification for Nitrile Examination Gloves for Medical Application) and 21 CFR 800.20. Gloves meet the current draft ASTM Standard Specification for Nitrile Examination Gloves for Medical Application. Test results also show that the product meets all the current specifications listed under the ASTM Specification D 3578 – 95, Standard Specification for Rubber Examination Gloves, <u>EXCEPT</u> for tensile strength and

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	<p>Gloves, EXCEPT for tensile strength and ultimate elongation requirements.</p> <p>Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization.</p> <p>Final product is negative for the presence of starch using the USP iodine test.</p>
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



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Goh See Knek
•Latexx Partners Berhad
PT 5054, Kamunting Industrial Estate
34600 Taiping Perak
MALAYSIA

Re: K981159
Trade Name: Proflex* Powder Free Nitrile Examination
Gloves
Regulatory Class: I
Product Code: LZA
Dated: March 21, 1998
Received: March 31, 1998

Dear Mr. Goh See Knek:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

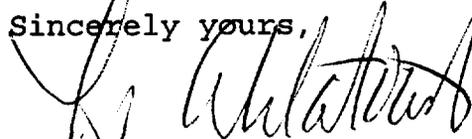
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21CFR 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/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 PARTNERS BHD.**
PT 5054, Kamunting Industrial Estate
P.O. Box 9
34600 Taiping Perak
MALAYSIA

510(k) Number : K 981159 *
(if known)

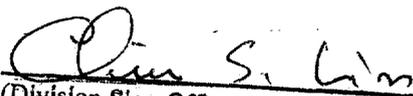
Device Name : **PROFLEX POWDERFREE NITRILE EXAMINATION GLOVE**

Indications For Use :

Proflex Powderfree 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)


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 981159

Prescription Use _____
Per 21 CFR 801.109

OR Over-The-Counter X