OCT - 1 2001

PT. SHAMROCK MANUFACTURING CORPORATION

Manufacturer of Latex & Nitrile Gloves

Jl. Raya Medan - Namorambe PS. IV Km. 9
Kab. Deli Serdang - Sumut - Indonesia
Tel: (62-61) 7030008 ; Fax : (62-61) 7030007

K012786

"510 (K)" SUMMARY

K012786

(1) Name of applicant : RUDY SALIM
Address : SHAMROCK Manufacturing Company
Jl. Raya Medan – Namorambe PS IV
Kabupaten Deli Serdang - Indonesia
Phone No. : 62-61-7030008
Fax No. : 62-61-7030007

Contact person in U.S.A : Emmy Tjoeng
Fax No. : 626-913-1498

(2) Device details
Trade Name : Powder free Nitrile Neoprene Examination Gloves

Classification Name : Powder free Nitrile Neoprene Examination Gloves

(3) Product Code : 80 LZA

(4) Equivalent device legally marketed : Class I Examination Gloves 80 LZA meeting ASTM D6319-00a

(5) Intended use : Powder free Nitrile Neoprene Examination Glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

(6) Technological characteristic of the gloves.

a. **Dimensions**

Sizes	Small	Medium	Large	X-Large
Length mm (min.)	220	230	230	230
Palm Width mm	80±10	95±10	111±10	120±10
Thickness				
1. Cuff mm (min)	0.05	0.05	0.05	0.05
2. Palm mm(min)	0.05	0.05	0.05	0.05
3. Finger Tip mm	0.05	0.05	0.05	0.05

b. **Physical Properties**

	Before ageing	After ageing at 70°C 168 hrs.
Tensile Strength	: 14 MPa (min)	14 MPa (min)
Ultimate Elongation	: 500 % (min.)	400 % (min.)

(7) Performance data is the same as mentioned immediately above.

(8) Clinical date is not needed for gloves or for most devices cleared by the 510 (K) process.

(9) Non-clinical data

We certify that the gloves meet or exceed ASTM D6319-00a Standard.
Meets FDA pinhole requirement.
Meets labeling claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Shamrock Manufacturing Company
C/O Ms. Emmy Tjoeng
889 Sotuh Azusa Avenue
City Of Industry, California 91748

Re: K012786
Trade/Device Name: Powder Free Nitrile Neoprene Examination Gloves (Purple)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: August 16, 2001
Received: August 20, 2001

Dear Ms, Tjoeng

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

PT. SHAMROCK MANUFACTURING CORPORATION

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ANNEXURE II

INDICATION FOR USE

Applicant : PT. SHAMROCK MANUFACTURING CORPORATION
Device Name : Powderfree Nitrile Neoprene Examination Gloves
Indication for use :

Powderfree Nitrile Neoprene Examination Glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

(signature)

RUDY SALIM
(Type Name)

Sept 14.01
(date)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012786