PT. Shamrock Manufacturing Corpora

K030134

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"510 (K)" SUMMARY

MAR 2 5 2003

(1) Name of applicant : DR. SUPENO SURYA, MBA PhD
Address : PT. SHAMROCK Manufacturing Corp.
Jl. Pemuda No. 11
Medan 20151 - Indonesia
Phone No. : 62-61-4558888
Fax No. : 62-61-4520588

Contact person in U.S.A : Emmy Tjoeng
Fax No. : 909-591-8878

(2) Device details
Trade Name : Latex Examination Gloves Powder Free with Neoprene Lined. Contains 50 mcgm or less of total Water Extractable Protein per gram

Classification Name : Latex Examination Gloves Powder Free with Neoprene Lined.

(3) Product Code : 80 LYY

(4) Equivalent device legally marketed : Class I Examination Gloves 80 LYY meeting ASTM D 3578-01ae2

(5) Intended use : Latex Examination Gloves Powder Free with Neoprene lined is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

OFFICE :
Jl. Pemuda No. 11 Medan - 20151 - Indonesia Phone (62-61) 455 8888 (Hunting) - 452 0688 - 452 6688 - 4520638
Fax. (62-61) 452 0588 E-mail : smc@shamrock-id.com

FACTORY :
Jl. Raya Medan - Namorambe Ps. IV Kab. Deli Serdang Phone (62-61) 703 0008 Fax. (62-61) 703 0007
E-mail : shamrock@indosat.net.id.

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(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)	0.08	0.08	0.08	0.08
2. Palm mm(min)	0.08	0.08	0.08	0.08
3. Finger Tip mm	0.08	0.08	0.08	0.08

b. Physical Properties

	Before ageing	After ageing at 70°C 168 hrs.
Tensile Strength	: 18 Mpa (min)	14 Mpa (min)
Ultimate Elongation	: 650 % (min.)	500 % (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 the ASTM D 3578-01ae2 Standard.
Meets FDA pin hole requirement.
Meets labeling claim.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

PT Shamrock Manufacturing Corporation
C/O Ms. Emmy Tjoeng
Marketing Director
Shamrock Manufacturing Company
5445 Daniels Street
Chino, California 91710

Re: K030134
Trade/Device Name: Latex Examination Gloves Powder Free with Neoprene Lined, Green Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: February 4, 2003
Received: March 3, 2003

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PT. Shamrock Manufacturing Corpora

ANNEXURE II

K030134

INDICATION FOR USE

Applicant : PT. SHAMROCK Manufacturing Corp.
Device Name : Latex Examination Gloves Powder Free with Neoprene lined
Indication for use : Contains 50 mcgm or less of total water Extractable Protein per gram

Latex Examination Glove Powder Free with Neoprene lined is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

(signature)

DR.SUPENO SURYA, MBA PhD

(Type Name)

JAN 03, 2003

(date)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030134