AUG 2 8 2003

K032294

APPENDIX M

510(k) SUMMARY

NON-STERILE POWDER-FREE ORANGE LATEX EXAMINATION GLOVES WITH OR WITHOUT ORANGE/VANILLA SCENTING PLUS A PROTEIN LABELING CLAIM (<50uG/G)
(Contains 50 micrograms or less of total water extractable protein per gram of glove)

Submitted For: **SGMP COMPANY LTD.**

Submitted By: **TUCKER & ASSOCIATES**
Official Correspondent for SGMP COMPANY LTD.
JANNA P. TUCKER, President – CEO
198 Avenue de la D'emerald
Sparks, NV 89434-9550
Phone: 775-342-2612
Fax: 775-342-2613
E-Mail: Tuckerjan@aol.com

Equivalent Predicate Device: POWDER FREE PURPLE LATEX EXAM GLOVES WITH AND WITHOUT GRAPE SCENTING which was approved for marketing as K011370.

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Device Information:

Trade Name: NON-STERILE POWDER FREE ORANGE LATEX EXAM GLOVES WITH/WITHOUT ORANGE/VANILLA SCENTING AND WITH PROTEIN LABELING (<50uG/G)

Common Name: Latex Exam Gloves.

Classification Name: Patient Examination Glove, Latex.

Classification Information & Device Description:

Class I latex patient examination glove, 80LYY, powder free And meeting all the requirements of ASTM D-3578-01aE2, Standard Specification for Latex Examination Gloves for Medical Application.

Intended Use of Device:

A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and the patient.

Technological Characteristics of Device:

1. Dimension

DIMENSION	ASTM D3578-01aE2	SGMP
X-Small Small Medium Large	70 mm +/- 10 mm 80 mm +/- 10mm 95 mm +/- 10mm 111mm +/- 10mm	70 - 75 mm 80 - 85 mm 90 - 97 mm 105 - 111 mm
Length	230 mm minimum for all sizes	242mm
Thickness - Finger Palm	0.08mm min 0.08mm min	0.08 mm min 0.08 mm min

2. Physical Properties (ASTM-D3578-01aE2 Standard Specification for Latex Exam Gloves)
on Lot# 0324

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-01aE2	SGMP	ASTM-D3578-01aE2	SGMP
	Mpa	Mpa	%	%
Before Aging	14.0		700	
X-Small		22.0		800
Small		28.1		850
Medium		30.2		900
Large		24.3		810
After Aging	14.0		500	
X-Small		25.4		800
Small		28.3		830
Medium		26.2		830
Large		24.6		800

3. Water Tight Test

Using the FDA specified 1,000 ml water leak test, 125 pieces of each size of the gloves were tested and our results are as given below:

BATCH #	SIZE	SAMPLE SIZE	LEAK STATUS	NUMBER LEAKED
UN-AGED				
0324	X-Small	125	Yes	1
0324	Small	125	No	0
0324	Medium	125	Yes	1
0324	Large	125	No	0
AGED				
0324	X-Small	125	Yes	1
0324	Small	125	No	0
0324	Medium	125	Yes	1
0324	Large	125	Yes	1

The above figures are within the ASTM D3578-01aE2 requirements for latex exam gloves of 2.5% AQL.

4. Biocompatibility

The bio-compatibility test results are as per attached in APPENDIX L and show that the gloves passed the tests for examination gloves.

5. Total Residual Powder Content & Presence of Cornstarch

TESTS	FDA INTERNAL REQUIREMENT	SGMP's
Residual Powder Content (ASTM D 6124-01)	2 mg/glove max	Range: 0.5-0.9mg/glove Mean : 0.7 mg/glove
Presence of Cornstarch	Negative	Negative

6. Residual Protein Level

TESTS	FDA ALLOWABLE LEVEL	CLAIMED LEVEL
ASTM D 5712-99	< 50 μg/g	< 50 μg/g

Conclusion:-

The data presented indicate that the Non-sterile Powder Free Orange latex examination glove with Orange/Vanilla Scenting

1. meets/exceeds ASTM- D3578-01aE2 Standard Specifications For Latex Examination Glove,

2. meets FDA pinhole requirements,

3. meets FDA claim criterion of a powder free glove.

4. meets the protein labeling claim level at <50 μg/g.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2003

SGMP Company Limited
C/O Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D' emerald
Sparks, Nevada 89434-9550

Re: K032294
Trade/Device Name: Non-Sterile Powder-Free Orange Latax Examination Glove with or without Orange/Vanilla Scenting Plus a Protein Labeling Claim (<50uG/G)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: July 23, 2003
Received: July 25, 2003

Dear Ms. Tucker:

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

INDICATION FOR USE STATEMENT

Applicant : SGMP Company Limited

510K NUMBER : K032294

Device Name : Non-sterile Powder Free Orange Latex Examination Gloves with or without Orange/Vanilla Scenting Plus A PROTEIN LABELING claim (≤50 ug/g) (Contains 50 micrograms or less of total water Extractable protein per gram

Indication For Use :

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

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

510(k) Number: K032294

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ..... **OR** **Over-The-Counter.....**
Per 21 CFR 801.109