SEP - 1 2005

K052016

APPENDIX L

510(k) SUMMARY

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR POWDER-FREE MULTICOLOR LATEX EXAMINATION GLOVES

Submitted For : SGMP Company Limited, 181 Moo 6, Tambol Kampaengpetch, Rattaphum, Songkhla 90180, Thailand.

Submitted By: Tucker & Associates
Official Correspondent for SGMP Co Ltd
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Equivalent Predicate Device: POWDER FREE BLUE LATEX EXAM GLOVES which was granted a 510(k) # K011377 and POWDER-FREE PINK LATEX EXAM GLOVES which was also granted a 510 (k) # K011371 as shown in APPENDIX M

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 MULTICOLOR LATEX EXAMINATION GLOVES
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I Latex patient examination glove 80LYY, powder free and meeting all the requirements of ASTM-D3578-01aE2 Standard Specification for Latex Examination Gloves for Medical Application.

Device Description:
Class I latex patient examination gloves 80LYY, powder free and meeting all the requirements of ASTM-D3578-01aE2 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 patient.

Technological Characteristics of Device:

1. Dimension

DIMENSION	ASTM D3578-01aE2	SGMP
X-Small Small Medium Large	70 mm +/- 10 mm 80 mm +/- 10 mm 95 mm +/- 10 mm 111 mm +/- 10 mm	70 – 80 mm 80 – 85 mm 90 – 97 mm 105 - 111 mm
Length	230 mm minimum for all sizes	242 mm
Thickness – Finger Palm	0.08 mm min 0.08 mm min	0.13 mm min 0.11 mm min

2. Physical Properties (ASTM-D3578-00aE2 Standard Specification for Latex Exam Gloves) on Lot# 4144

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-00aE2	SGMP	ASTM-D378-00aE2	SGMP
	Mpa	Mpa	%	%
Before Aging	18.0		650	
X-Small		23.5		890
Small		26.8		800
Medium		22.5		850
Large		29.2		870
After Aging	14.0		500	
X-Small		22.8		780
Small		27.5		820
Medium		28.3		750
Large		26.8		820

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				
4144	X-Small	125	No	0
4144	Small	125	Yes	1
4144	Medium	125	Yes	2
4144	Large	125	No	0
AGED				
4144	X-Small	125	No	0
4144	Small	125	Yes	1
4144	Medium	125	Yes	1
4144	Large	125	Yes	2

The above figures are within the ASTM D3578-00aE2 requirements for latex exam gloves of 2.5% AQL.

4. Biocompatibility

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

5. Total Residual Powder Content & Presence of Cornstarch

TEST	FDA REQUIREMENT	INTERNAL SGMP's
Residual Powder Content (ASTM D 6124-00)	2 mg/glove max	Ranger : 0.4 – 1.0 mg/glove Mean : 0.8 mg/glove
Presence of Cornstarch	Negative	Negative

6. **Residual Protein Level.**

TEST	FDA ALLOW ABLE LEVEL	CLAIMED LEVEL
ASTM D 5712-99	< 50 $\mu g/dm^2$	< 50 $\mu g/ dm^2$

Conclusion:-

The data presented indicate that the Non-sterile Powder Free Multicolor Latex Examination Gloves.

1. meets/exceeds ASTM- D3578-00aE2 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 labelling claims level at <50 $\mu g/ dm^2$

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 1 2005

SGMP Company Limited
C/O Janna P. Tucker
Tucker & Associates
198 Avenue De La D'Emerald
Sparks, Nevada 89434

Re: K052016
Trade/Device Name: Non-Sterile, Latex, Powder-Free Patient Examination Glove (Multicolored), with Protein Labeling Claim (50 Micrograms or Less)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 9, 2005
Received: August 25, 2005

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: SGMP Company Ltd.

510(k) Number (if known): K052016

Device Name: Non-Sterile, Latex, Powder-Free Patient Examination Gloves (Multicolored), with Protein Labeling Claim (50 Micrograms or less)

Indications For Use:

The Non-Sterile, Latex, Powder-Free Patient Examination Gloves (Multicolored), with Protein Labeling Claim (50 Micrograms or less) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila F. Murphy M.D. 8/31/05

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

510(k) Number: K052016