

MAR 21 2008

K 072406

APPENDIX L

**510(k) SUMMARY**  
SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR  
POWDER FREE PINK LATEX EXAMINATION GLOVES WITH CHERRY FLAVOUR  
AND WITH PROTEIN LABELING CLAIMS (50 MICROGRAMS OR LESS)

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

**Submitted By:** Tucker & Associates  
Official Correspondent for SGMP Co Ltd  
Janna P. Tucker, President – CEO  
198 Avenue de la D'emerald, Sparks, NV 89434-9550  
Phone No : 775-342-2612 Fax No : 775-342-2613  
E-mail: Tuckerjan@aol.com

**Equivalent Predicate Device:** POWDER FREE LATEX EXAM GLOVES which was granted a 510(k) # K011371

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 Pink Latex Examination Gloves with Cherry Flavour and with protein labeling claims (50 Micrograms or less)

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-D3578-05 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-D3578-05 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.

K072406

Technological Characteristics of Device:

1. Dimension

DIMENSION	ASTM D3578-05	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	240 mm
Thickness – Finger Palm	0.08 mm min 0.08 mm min	0.13 mm min 0.10 mm min

2. Physical Properties (ASTM-D3578-05 Standard Specification for Latex Exam Gloves)  
on Lot# 7023

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-05	SGMP	ASTM-D3578-05	SGMP
<b>Before Aging</b>	Mpa 18.0	Mpa	% 650	%
X-Small		25.1		830
Small		22.8		870
Medium		28.0		850
Large		26.3		855
<b>After Aging</b>	14.0		500	
X-Small		24.5		790
Small		23.5		805
Medium		26.0		780
Large		25.2		770

K072406

**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				
7023	X-Small	125	No	0
7023	Small	125	Yes	2
7023	Medium	125	Yes	1
7023	Large	125	Yes	1
AGED				
7023	X-Small	125	Yes	2
7023	Small	125	No	0
7023	Medium	125	Yes	1
7023	Large	125	No	0

The above figures are within the ASTM D3578-05 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 6124-06)	10 mg/glove max	Ranger : 0.8-1.7 mg/glove Mean : 1.4 mg / glove
Presence of Cornstarch	Negative	Negative

**6. Residual Protein Level.**

Test	FDA Allow Able level	Claimed Level
ASTM D 5712-99	< 50 µg/dm <sup>2</sup>	< 50 µg/ dm <sup>2</sup>



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 21 2008**

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

Re: K072406

Trade/Device Name: Non-Sterile, Powder Free Pink Latex Examination Gloves with  
Cherry Flavour and with Protein Labeling Claims (50 Micrograms or Less)

Regulation Number: 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LYY

Dated: March 11, 2008

Received: March 13, 2008

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.

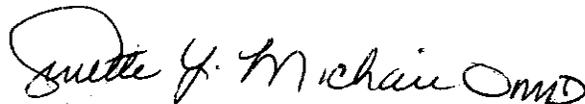
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

## INDICATION FOR USE STATEMENT

Applicant : SGMP Company Limited

510K NUMBER : K 072406

Device Name : Non-Sterile, Powder Free Pink Latex Examination Gloves with Cherry Flavour and with protein labeling claims (50 Micrograms or less)

Indication For Use :

The Non-Sterile, Powder Free Pink Latex Examination Gloves with Cherry Flavour and with protein labeling claims (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 .....  
(Part 21 CFR 801.Subpart D)

AND / OR

Over-The-Counter.....  
21 CFR 801 Subpart C

.....  
Concurrence of CDRH , Office of Device Evaluation (ODE)

Shirley B. Murphy MD  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K072406