

SEP 21 2001

KO12860

APPENDIX M

510(k) SUMMARY

**SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR
POWDER FREE CHOCOLATE SCENTED LATEX EXAMINATION GLOVES**

Contact person : Cheah Chor Hee

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

Device Information:

Trade Name – NON-STERILE POWDER FREE CHOCOLATE SCENTED 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-D3578-00 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-D3578-00 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 D3578-00	SGMP
X-Small	70 mm +/- 10 mm	70 - 75 mm
Small	80 mm +/- 10mm	80 - 85 mm
Medium	95 mm +/- 10mm	90 - 97 mm
Large	111mm +/- 10mm	105 - 111 mm
Length	230 mm minimum for all sizes	252mm
Thickness - Finger Palm	0.08mm min 0.08mm min	0.08 mm min 0.08 mm min

K012860

2. Physical Properties (ASTM-D3578-00 Standard Specification for Latex Exam Gloves) on Lot# 1125

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-00	SGMP	ASTM-D3578-00	SGMP
	Mpa	Mpa	%	%
Before Aging	14.0		700	
X-Small		27.5		850
Small		24.3		810
Medium		24.5		810
Large		24.7		810
After Aging	14.0		500	
X-Small		29.5		930
Small		19.5		790
Medium		23.6		820
Large		26.5		900

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
1125				
UN-AGED	X-Small	125	No	0
	Small	125	Yes	1
	Medium	125	Yes	2
	Large	125	Yes	1
AGED	X-Small	125	Yes	1
	Small	125	No	0
	Medium	125	Yes	3
	Large	125	No	0

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

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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 6124-00)	2 mg/glove max	Range: 0.8-1.6mg/glove Mean : 1.2 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 Chocolate Scented latex examination glove

1. meets/exceeds ASTM- D3578-00 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.



SEP 21 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K012860

Trade/Device Name: Powder-Free Latex Examination Gloves with Chocolate
Scenting and Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: August 23, 2001
Received: August 23, 2001

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.

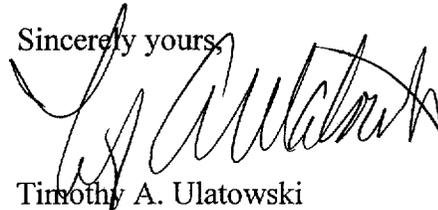
Please be advised that FDA's issuance of a substantial equivalence determination does not

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 (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 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 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

INDICATION FOR USE STATEMENT

Applicant : SGMP Company Limited

510K NUMBER : *K012860*

Device Name : *Non-sterile Powder Free Latex Examination Gloves with Chocolate Scent AND PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)*

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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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use
Per 21 CFR 801.109

OR

Over-The-Counter.....

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number *K012860*