JUN - 7 2001

K 011377

**APPENDIX M**

**510(k) SUMMARY**

SUMMARY OF THE SAFETY AND EFFECTIVENESS FORPOWDER FREE BLUE LATEX EXAMINATION GLOVES WITH & WITHOUT BUBBLEGUM SCENT

**Contact person** : Cheah Chor Hee

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 BLUE LATEX EXAM GLOVES
NON-STERILE POWDER FREE BLUE LATEX EXAM GLOVES WITH BUBBLEGUM SCENT
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-D3578-99 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-D3578-99 Standard Specification for Latex Examination Gloves for Medical use.

**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 D3578-99 | SGMP |
|---|---|---|
| X-Small<br>Small<br>Medium<br>Large | 70 mm +/- 10 mm<br>80 mm +/- 10mm<br>95 mm +/- 10mm<br>111mm +/- 10mm | 70 - 75 mm<br>80 - 85 mm<br>90 - 97 mm<br>105 - 111 mm |
| Length | 230 mm minimum for all sizes | 245mm |
| Thickness - Finger<br>Palm | 0.08mm min<br>0.08mm min | 0.08 mm min<br>0.08 mm min |

2. **Physical Properties (ASTM-D3578-99 Standard Specification for Latex Exam Gloves) on Lot# 0070**

| | TENSILE STRENGTH | | ULTIMATE ELONGATION | |
|---|---|---|---|---|
| | ASTM-D3578-99 | SGMP | ASTM-D3578-99 | SGMP |
| | Mpa | Mpa | % | % |
| **Before Aging** | 14.0 | | 700 | |
| X-Small | | 26.9 | | 900 |
| Small | | 27.2 | | 860 |
| Medium | | 29.6 | | 910 |
| Large | | 25.9 | | 820 |
| **After Aging** | 14.0 | | 500 | |
| X-Small | | 24.4 | | 910 |
| Small | | 26.9 | | 940 |
| Medium | | 24.3 | | 950 |
| Large | | 23.2 | | 830 |

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** | | | | |
| 0070 | X-Small | 125 | Yes | 2 |
| 0070 | Small | 125 | Yes | 1 |
| 0070 | Medium | 125 | Yes | 2 |
| 0070 | Large | 125 | Yes | 1 |
| **AGED** | | | | |
| 0070 | X-Small | 125 | No | 0 |
| 0070 | Small | 125 | Yes | 1 |
| 0070 | Medium | 125 | Yes | 1 |
| 0070 | Large | 125 | No | 0 |

The above figures are within the draft FDA/ASTM D3578-99 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 6124-00) | 2 mg/glove max | Range: 0.4-0.9g/glove<br>Mean : 0.6mg/glove |
| Presence of Cornstarch | Negative | Negative |

## 6. Residual Protein Level

| TESTS | FDA ALLOWABLE LEVEL | CLAIMED LEVEL |
|---|---|---|
| ASTM D 5712-95 | < 50 μg/g | < 50 μg/g |

**Conclusion:-**

The data presented indicate that the Non-sterile Powder Free Blue latex examination glove with and without bubblegum scent

1. meets/exceeds ASTM- D3578-99 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

JUN - 7 2001

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

Re: K011377
Trade/Device Name: Non-Sterile Powder-Free Blue Latex Examination Gloves, with and without Bubble Gum Scent and with Protein Labeling Claim (50 microgram or less per gram)
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: May 2, 2001
Received: May 4, 2001

Dear Ms. Tucker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

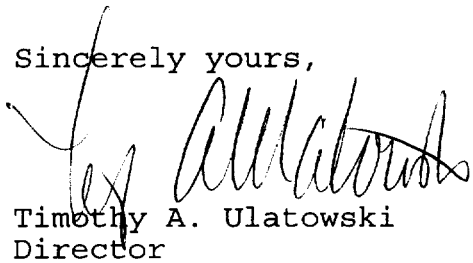
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that,

through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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 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 :** K011377

**Device Name : Non-sterile Powder Free Blue Latex Examination Gloves with & without Bubblegum Scent** contains 50mcgm or less of Total 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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**Concurrence of CDRH Office of Device Evaluation (ODE)**

**Prescription Use** ..... **OR** **Over-The-Counter** X .....

**Per 21 CFR 801.109**



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011377