

K992419

**APPENDIX F****510(k) SUMMARY****SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR ROYAL SHIELD BLUE  
COLORED POWDERED LATEX EXAMINATION GLOVES WITH AND WITHOUT  
BUBBLEGUM SCENTING & A PROTEIN LABELLING CLAIM****Contact person :** Ong Lay Mau

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

**Device Information:**

Trade Name - ROYAL SHIELD COLORED POWDERED 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, powdered 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, powdered and meeting all the requirements of ASTM-D3578-99 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.

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**Technological Characteristics of Device:****1. Dimension**

| DIMENSION                  |             |                 |                   |
|----------------------------|-------------|-----------------|-------------------|
| Width                      |             | Ambidextrous    | Size Fitted       |
|                            | X-Small     | 70 mm +/- 10 mm | 5.5 70 +/- 10 mm  |
|                            | Small       | 80 mm +/- 10mm  | 6.0 76 +/- 10mm   |
|                            | Medium      | 95 mm +/- 10mm  | 6.5 83 +/- 10mm   |
|                            | Large       | 111mm +/- 10mm  | 7.0 89 +/- 10mm   |
|                            |             |                 | 7.5 95 +/- 10mm   |
|                            |             |                 | 8.0 102 +/- 10mm  |
|                            |             |                 | 8.5 108 +/- 10 mm |
| 9.0 114 +/- 10mm           |             |                 |                   |
| Length                     | 230 mm      |                 |                   |
| Thickness - Finger<br>Palm | 0.08 mm min |                 |                   |
|                            | 0.08 mm min |                 |                   |

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

| DATE<br>TESTED | TENSILE STRENGTH |      |        |      | ULTIMATE ELONGATION |      |        |      |
|----------------|------------------|------|--------|------|---------------------|------|--------|------|
|                | AGED             |      | UNAGED |      | AGED                |      | UNAGED |      |
|                | SHIELD           | ASTM | SHIELD | ASTM | SHIELD              | ASTM | SHIELD | ASTM |
| 20 May 99      | 27.7             | 14.0 | 24.3   | 14.0 | 950                 | 500  | 900    | 700  |
| 20 May 99      | 25.2             | 14.0 | 30.3   | 14.0 | 900                 | 500  | 900    | 700  |
| 20 May 99      | 29.1             | 14.0 | 30.1   | 14.0 | 950                 | 500  | 900    | 700  |

## 3. Water Tight Test Results\*

| BATCH #     | DATE<br>TESTED | SAMPLE SIZE | LEAK STATUS | NUMBER<br>LEAKED |
|-------------|----------------|-------------|-------------|------------------|
| 9028-9035 S | 15 May 99      | 315         | Yes         | 4                |
| 9030-9036 M | 19 May 99      | 315         | Yes         | 7                |
| 9027-9031 L | 19 May 99      | 200         | Yes         | 3                |

\* # APO3151/52

The above figures are within the ASTM D-3578-99 requirements for latex exam gloves of 2.5% AQL.

## 4. Biocompatibility

The test results below show that the gloves meet FDA biocompatibility requirements:

### BIOCOMPATIBILITY TESTS

Primary Dermal Irritation Test

Skin Sensitization Study

### RESULTS

Not a primary irritant

Not a sensitiser

## 5. Residual Protein Level

| TESTS          | FDA ALLOWABLE LEVEL | CLAIMED LEVEL                 |
|----------------|---------------------|-------------------------------|
| ASTM D 5712-95 | -                   | < 200 µg/g<br>Range:<br>Mean: |

The data presented indicate that the Royal Shield Powdered latex examination glove

1. meets/exceeds ASTM- D3578-99 Standard Specifications For Latex Examination Glove,
2. meets FDA pinhole requirements,
3. meets the protein labeling claim level at <200 µg/g.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 13 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Shield Gloves Manufacturer (M) Sdn. Bhd.  
C/O Mr. E. J. Smith  
Consultant  
Smith Associates  
P.O. Box 4341  
Crofton, Maryland 21114

Re: K992419  
Trade Name: Royal Shield Non-Sterile Blue Powdered Latex  
Examination Gloves with Protein Content Labeling Claim  
(200 Micrograms or Less of Total Water Extractable  
Protein per gram) with or without Bubble Gum Scent  
Regulatory Class: I  
Product Code: LYY  
Dated: July 16, 1999  
Received: July 20, 1999

Dear Mr. Smith:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

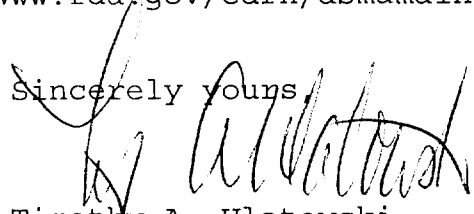
Page 2 - Mr. Smith

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" (21 CFR 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/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

**INDICATIONS FOR USE STATEMENT**

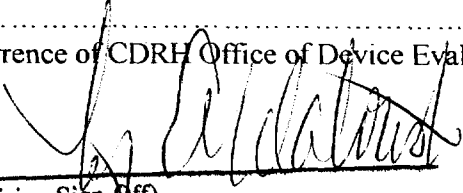
Applicant: Shield Gloves Manufacturer (M) Sdn Bhd.

510K Number: K992419

Device Name: Royal Shield Powdered Latex Examination Gloves Blue Color With or With.  
Bubble Gum Scent, Contains 200 mcgm or less of Total Water extractable  
Indications For Use : protein per gram.

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)

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

510(k) Number K992419

Prescription Use .....  
Per 21 CFR 801.109

OR

Over-The-Counter.....  
✓