SEP 13 1999

K992417

APPENDIX H

510(k) SUMMARY

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR
ROYAL SHIELD POWDERED LATEX EXAMINATION GLOVES

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 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.

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				
	Ambidextrous		Size Fitted	
Width	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	0.08 mm min			
Palm	0.08 mm min			

2. Physical Properties (ASTM-D3578-99 Standard Specification for Latex Exam Gloves) After Real Time Ageing On Gloves Produced in 1994.

Batch # 9410243147 & 9411153155

DATE	TENSILE STRENGTH				ULTIMATE ELONGATION			
	AGED		UNAGED		AGED		UNAGED	
TESTED	SHIELD	ASTM	SHIELD	ASTM	SHIELD	ASTM	SHIELD	ASTM
10.3.97	21.8	14.0	25.1	14.0	975	500	922	700
10.3.98	27.3	14.0	27.3	14.0	877	500	790	700
11.3.99	22.0	14.0	26.2	14.0	928	500	854	700

3. Water Tight Test After Real Time Ageing

Using the FDA specified 1,000 ml water leak test, 80 pieces of the gloves produced in 1994 over a period of three years of storage were tested and our results are as given below:

BATCH #	DATE TESTED	SAMPLE SIZE	LEAK STATUS	NUMBER LEAKED
9410243147/	Mar 10, 1997	125	Yes	2
9411153155	Mar 10, 1998	125	Yes	1
Size L/R 6.0	Mar 11, 1999	125	Yes	2

The above figures are within the FDA/draft ASTM 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	RESULTS
Primary Dermal Irritation Test	Not a primary irritant
Skin Sensitization Study	Not a sensitiser

5. Residual Protein Level

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

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

1. meets/exceeds ASTM- D3578-95 Standard Specifications For Latex Examination Glove,
2. meets FDA pinhole requirements,
3. meets SHIELD's shelf life labeling claim of four years,
4. meets the protein labeling claim level at <200 µg/g.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 1999

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

Re: K992417
Trade Name: Royal Shield Non-Sterile Powdered Latex Examination Gloves with Protein Labeling Claim (200 Micrograms or Less of Total Water Extractable Protein per gram)
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

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: K992417

Device Name: Royal Shield Powdered Latex Examination Gloves - Protein Content 200 mcgm or less of total water extractable protein per gram

Indications 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.

.....

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ..... OR Over-The-Counter ✓.....
Per 21 CFR 801.109

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992417