

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	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 Palm	0.08 mm min	
	0.08 mm min	

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

DATE 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 TESTED	SAMPLE SIZE	LEAK STATUS	NUMBER 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	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- D3578-99 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

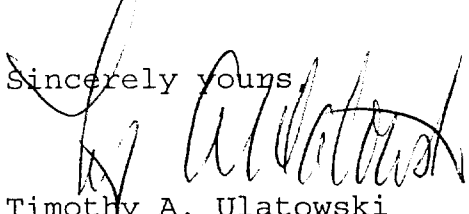
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premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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.

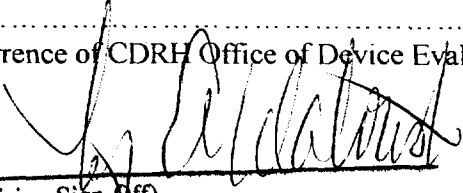
510K Number: K992419

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 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.

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Concurrence of CDRH Office of Device Evaluation (ODE)



(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.....
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