SEP 1 7 2001

K011613

APPENDIX K

510(k) SUMMARY

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR POWDER-FREE, "BARRIER-PRO™", SYNTHETIC BUTADIENE CO-POLYMER EXAM GLOVES, COLOR: GREEN

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 - **See above complete title for this exam glove.**
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information -.Class I latex patient examination glove 80LZA powder free and meeting all the requirements of ASTM-D3578-01 Standard Specification for Latex Examination Gloves for Medical Application (except for the elongation at break parameter.

Device Description:
Class I latex patient examination glove 80LZA, powder free and meeting all the requirements of ASTM-D3578-01 Standard Specification for Latex Examination Gloves for Medical Application, except for the elongation at break parameter.

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	Shield Gloves
X-Small Small Medium Large	70 mm +/- 10 mm 80 mm +/- 10mm 95 mm +/- 10mm 111mm +/- 10mm	70 - 75 mm 80 - 85 mm 90 - 97 mm 105 - 111 mm
Length	230 mm minimum for all sizes	242mm
Thickness - Finger Palm	0.08mm min 0.08mm min	0.08 mm min 0.08 mm min

(Revised 8-9-01)
(Revised 9-10-01)

2. **Physical Properties (ASTM-D3578-00 Standard Specification for Latex Exam Gloves) on Lot# 1128**

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-00	SGMP	ASTM-D3578-00	SGMP
	Mpa	Mpa	%	%
Before Aging	14.0		700	
X-Small		25.3		840
Small		26.0		850
Medium		28.9		860
Large		22.0		840
After Aging	14.0		500	
X-Small		21.3		890
Small		23.4		930
Medium		23.6		940
Large		21.7		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 # 1128	SIZE	SAMPLE SIZE	LEAK STATUS	NUMBER LEAKED
UN-AGED				
	X-Small	125	Yes	2
	Small	125	No	0
	Medium	125	Yes	1
	Large	125	No	0
AGED				
	X-Small	125	Yes	1
	Small	125	Yes	2
	Medium	125	Yes	1
	Large	125	No	0

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

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4. Biocompatibility

The bio-compatibility test results show that the glove is neither a dermal irritant nor a skin sensitizer.

5. Total Residual Powder Content & Presence of Cornstarch

TESTS REQUIREMENT	FDA	Shield's
Residual Powder Content (ASTM D 6124-00)	2 mg/glove max	Range: 0.7-1.5mg/glove Mean : 1.05 mg/glove
Presence of Cornstarch	Negative	Negative

Conclusion:-

The data presented indicate that this Synthetic Butadiene Co-Polymer glove:

1. meets/exceeds ASTM- D3578-[redacted] Standard Specifications For Latex Examination Glove, except for the elongation at break parameter,
2. meets FDA pinhole requirements,
3. meets FDA claim criterion of a powder free glove,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2001

Shield Gloves Manufacturing (M) Sdn Bhd
C/O Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K011613
Trade/Device Name: Powder-Free Green "Barrier-Pro™" Synthetic Butadiene Copolymer Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: July 9, 2001
Received: July 13, 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.

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

INDICATIONS FOR USE STATEMENT

Applicant: Shield Gloves Manufacturer (M) Sdn. Bhd.

510K Number: K011613

Device Name: **NON-STERILE, POWDER-FREE, "BARRIER-PRO™" SYNTHETIC BUTADIENE CO-POLYMER EXAM GLOVES, COLOR: GREEN**

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)

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

(Revised 9-10-01)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011613