JUN 6 2002

Attachment 3

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K013980

1. Submitter's Identification:

Safe Shield Co. Ltd.
43/2, K.M. 28, Surat-Takuapa Road
Tambon: Bangduen, Amphur: Phun Phin
Suratthani 84100, Thailand

Contact: Mr. Krishan Kumar Dwivedy, Managing Director of Safe Shield

Date Summary Prepared: April 17, 2002

2. Name of the Device:

Safe Shield Pre-Powdered Latex Examination Gloves

3. Predicate Device Information:

K#973831, Pre-Powdered Patient Examination Gloves, Safe-Glove Ltd., Glendale, AZ

4. Device Description:

Patient Examination Gloves are a Class I device 21 CFR 880. These gloves are pre-powdered with a PMA approved Corn Starch Powder. They are used for wearing on hands of healthcare providers to prevent contamination from patient's or external environment.

The standards that are followed are as follows: ASTM 3578-00 and Food and Drug requirements for Patient Examination Gloves.

5. Intended Use:

This latex examination glove is a disposable device intended for medical purposes in that it is worn on hands of health care providers or examiner's hand to prevent contamination between patient and examiner.

6. Comparison to Predicate Devices:

The Safe Shield latex examination gloves are substantially equivalent in specifications, testing parameters, quality inspections and other physical attributes to Safe Gloves Co., Ltd. latex examination gloves and intended for same usages. There are no special labeling claims made for these gloves.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The physical specifications are as follows:

Length: 230 mm minimum

Thickness: 0.08 mm minimum

Width:

Small:	80 ± 10 mm
Medium:	95 ± 10 mm
Large:	110 ± 10 mm

Physical Properties: (Minimum)

	Before Aging	After Aging
Tensile Strength	21 Mpa	16 Mpa
Ultimate Elongation	700%	500%

Sampling and AQLs:

	Sampling	AQL
Water Tight Test	G-II	2.5
Dimensions	S-2	4.0
Physical Properties	S-2	4.0

PIN HOLE TESTING: Pin hole testing is done in conformance with Food and Drug Administration's requirement of 1000 ml Water fill test method as described in Paragraph (b) Test method of the final rule entitled Patient Examination gloves and test Method for leakage defects: Adulteration, 55 CFR 51256 - 51258, 21 CFR 800.20, The sampling plan is derived from MIL-STD-105E (MILITARY STANDARD FOR SAMPLING PROCEDURES AND TABLES FOR INSPECTION BY ATTRIBUTES) based on General Inspection Level G II, normal inspection and acceptable quality level of 4.0

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The Safe Shield latex examination gloves are substantially equivalent in specifications, testing parameters, quality inspections and other physical attributes to Safe Gloves Co., Ltd. latex examination gloves and intended for same usages. There are no special labeling claims made for these gloves.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

Safe Shield Company Limited
C/O Ms. Susan Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K013980
Trade/Device Name: Safe Shield Pre-Powdered Latex Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: April 17, 2002
Received: April 19, 2002

Dear Ms. Flak:

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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements 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 (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 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,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement: Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE

Applicant: Safe Shield Co. Ltd.

510(k) Number (if known):* K013980

Device Name: Safe Shield Pre-Powdered Latex Examination Gloves

Indications For Use:

A Pre-Powdered Latex Examination Glove is a disposable device that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter _____
Per 21 CRF 801.109
(Optional Format 11-2-96)

* For a new submission, do **NOT** fill in the 510(k) number.

Clin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013980