Kemwell International Ltd.
3-B, II PHASE, PEENYA
BANGALORE 560 058, INDIA
PH : 91-80-8395701/8392354
TLX : 845-5078 KIPL IN
FAX : 91-80-8391450/8396345

KEMWELL

APR - 3 1998

K980803

Attachment I

510(k) SUMMARY

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is :

1. Submitter's identification	C ALVA Kemwell International Ltd. 3-B, Peenya, II Phase Bangalore 560 058, INDIA.
Date Summary prepared	February 9, 1998
2. Name of the Device	Sterile Powder-Free Latex Examination Gloves
3. Predicate Device Information	Class I powder-free Latex Examination Gloves which meets the requirements of ASTM D 3578-95. The equivalent device identified in the market is the powder-free examination gloves marketed by SAFESKIN Corporation, USA.
4. Device Description	Classified by FDA's General and Plastic Surgery Device Panel as Class 1, 21 CFR 878.4460, Examination Powder-free Latex Gloves, 80 LYY and meets all requirements of ASTM standard D-3578-95.
5. Intended Use	This device is intended to be used as a single use disposable sterile examination glove.
6. Comparison to Predicate Devices	Kemwell International Ltd. Powder-free Latex Examination Gloves is substantially equivalent in safety and effectiveness to the powder-free examination gloves sold by Safeskin Corporation USA.

..2..

Kemwell International Ltd.
3-B, II PHASE, PEENYA
BANGALORE 560 058, INDIA
PH : 91-80-8395701/8392354
TLX : 845-5078 KIPL IN
FAX : 91-80-8391450/8396345

KEMWELL

7. Discussion of Non-clinical Tests performed for determination of substantial equivalence are as follows:

The standards used for Sterile Powder-Free Latex Examination Gloves production are based on ASTM-D-3578-95. All tests meet requirements of Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 1.5, Inspection Level 1 meeting these requirements. Primary skin Irritation and Skin sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritation or sensitization reactions.

There are no special labelling claims and we do not claim our gloves as hypoallergenic on our labels.

Kemwell International Ltd., operates in compliance with FDA's GMPs.

8. Discussion of Clinical Tests Performed:

Not applicable - there is no hypoallergenic claim.

9. Conclusions:

Kemwell International Ltd. Sterile Powder-Free Latex Examination Glove conform fully o ASTM-D-3578-95 standards as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in our 510(k). There are no safety/efficacy issues or new claims from the 'Substantial equivalence" products cited

Based on the non-clinical tests our product has demonstrated to be as safe as effective as our predicate device.

For KEMWELL INTERNATIONAL LTD.

C.ALVA
GENERAL MANAGER (TECH.)

Date: February 9, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1998

Kemwell International, Ltd.
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent for Kemwell International Ltd.
MDI Consultants
55 Northern Boulevard, Suite 410
Great Neck, New York 11021

Re: K980803
Trade Name: Powder-Free Sterile Latex Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: February 26, 1998
Received: March 2, 1998

Dear Ms. Goldstein-Falk:

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

510(k) Number (if known): K980803

Device Name: Sterile Powder-Free Latex Examination Gloves

Indications For Use:

This Examination Glove is a device made of natural rubber latex intended to be worn by medical personnel to prevent cross contamination between them and the patient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980803

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)