

APR - 8 1998

K980412**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 January 19, 1998

2. Name of the Device Coloured Powder-free Latex Surgical
Gloves.

3. Predicate Device Information Class I powder-free Latex Surgical Gloves
which meets the requirements of ASTM D
3577-91. The equivalent device identified in
the market is SAFESKIN-SUPRA of
Safeskin Corporation, USA(This product is
of natural colour).

4. Device Description Classified by FDA's General and Plastic
Surgery Device Panel as Class 1, 21 CFR
878.4460, Surgical Powder-free Latex
Gloves, 79KGO and meets all requirements
of ASTM standard D-3577-91.

5. Intended Use This device is intended to be used as a single
use disposable sterile surgical glove.

6. Comparison to Predicate Devices Kemwell International Ltd. Powder-free
Latex Surgical Gloves is substantially
equivalent in safety and effectiveness to the
gloves sold by Safeskin Corporation USA,
the brand name SAFESKIN-SUPRA.

KEMWELL

Kemwell International Ltd.
3-B, II PHASE, PEENYA
BANGALORE 560 058, INDIA
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TLX : 845-5078 KIPL IN
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7. Discussion of Non-clinical Tests performed for determination of substantial equivalence are as follows:

The standards used for Coloured Powder-free Latex Surgical Gloves production are based on ASTM-D-3577-91. All test 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. Coloured Powder-free Latex Surgeon's Glove conform fully to ASTM-D-3577-91 standards as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labelling 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.,

SIGNATURE:



C. ALVA,
General Manager (Technical)

DATE:19-1-1998



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 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: K980412
Trade Name: Green Powder-Free Latex Surgical Gloves
Regulatory Class: I
Product Code: KGo
Dated: January 29, 1998
Received: February 3, 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 (Pre-market 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 pre-market 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): K980412

Device Name: Green
~~Coloured~~ Powder-free Latex Gloves

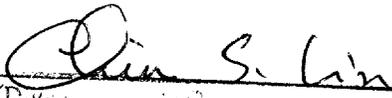
Surgeon's

Indications For Use:

This Surgeon's Glove is a device made of natural rubber latex intended to be worn by operating room personnel to protect a surgical wound from contamination.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Director, Center for Device Evaluation,
and General Hospital Devices

510(k) Number K980412

Prescription Use _____
(Per 21 CFR 801.109)

CR

Over-The-Counter Use X

(Optional Format 1-2-96)