

NOV 27 1996

Exhibit #1
Page 1 of 3**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: K963020

1. Submitter's Identification: C. Alva
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Date Summary Prepared: 10th July 1996
2. Name of the Device: GLOVEL Gx 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.
4. Device Description: Classification 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.

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6. Comparison to Predicate
Device:

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.

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

The standards used for Glovel Gx, Powder-free Latex Surgical Gloves production are based on ASTM-D-3577-91. 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 I meeting these requirements. Primary Skin Irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

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

Method of Sterilization: Ethylene Oxide

Methodology Used: EN550 Equivalent to AAMI/ANSI/ISO-11145-1994 Standard.

Sterility Assurance Level: 10^{-6}

Parameters Employed:

ETO Concentration: 750 mg/L

Exposure Time: 6 hrs.
Temperature: 55-60°C
RH: 50% (min)

8. Discussion of Clinical Tests Performed:

Not applicable - there is no hypoallergenic claim.

9. Conclusion:

Kemwell International Ltd. Powder-free Latex Surgeon's Gloves conform fully to ASTM-D-3577-91 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 and effective as our predicate device.