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K962139

Safeskin Corporation
Submitted: May 28, 1996
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Attachment 8
510(k) Summary
of Safety and Effectiveness



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**Hypoallergenic Powder-Free
Nitrile Examination Gloves**

**510 (K) SUMMARY
of Safety and Effectiveness**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. [807.92(c)] **Separate Document**

2. [807.92(a)] **Applicant:** Safeskin Corporation
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3. [CFR 880.6250] **Date Summary Prepared:** May 28, 1996

Name of Device:

- Proprietary Name: Safeskin
- Common Name: Nitrile exam gloves
- Classification: Patient examination glove (per 21CFR 880.6250)

4. [807.92 (a)(3)] **Equivalence:**

The legally marketed device to which equivalence is claimed is K932404 (Safeskin) a Class I Nitrile patient examination glove 80 FMC.

5. [807.92(a)(4)]

Description:

This Class I Nitrile patient examination glove (80FMC) is powder-free and meets all the requirements of ASTM Standard D 3578-91 with the exception of pre-aged ultimate elongation. This applicant glove, does however, far exceed the requirements for the only synthetic (non-natural latex) examination glove requirements as described in ASTM D 5250-92. The glove is the same product to which equivalence is claimed, K932404 (Safeskin), except colorant and the Hypoallergenic claim have been added.

Similarity and Differences
Comparison Between Safeskin's K932404
and This New Submission

	Same	Different
Formulation	✓	
Processing	✓	
Powder-Free	✓	
Non-Sterile	✓	
Biocompatibility	✓	
Physical Testing	✓	
Hypoallergenic		✓
Colorant		✓

6. [807.92(a)(5)]

Intended Use:

A glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

7. [807.92(a)(6)]

Technological Characteristics of applicant device compared to predicate device; non-clinical performance data:

Both gloves comply with ASTM 3578-91 Standard and the FDA Water Leak Test.

- A. Gloves comply with ASTM D3578-91 and FDA 1,000 mL Water Leak requirement.
- B. The powder-free assessment which follows is based upon the procedure:

Tests for Particulates by Weight and Iodine Color as described on pg. 5.54 in Regulatory Requirements for Medical gloves by the Division of Small Manufacturers Assistance, CDRH, FDA, May 1993.

B. Powder-free Assessment	COMPARISON		
		K932404	Applicant Device
Residue weight	≤ 2 mg	same glove	same glove
Results of iodine assay (cornstarch)	< 5 mg	same glove	same glove

C. Biocompatibility As recommended by the Tripartite Guidance on Biocompatibility of Medical Devices	COMPARISON	
	K932404	Applicant Device
	Pass/Fail	
• <u>Primary Dermal Irritation</u> Consumer Product Safety Commission, Title 16, Chapter II, Part 1500	Pass	Pass
• <u>Dermal Sensitization (Buehler) Study</u> <i>ASTM Standard F 720-81 (Reapproved in 1986)</i>	Pass	Pass
• <u>200 Person Modified Draize Test</u> <i>DSMA Regulatory Requirements for Medical Gloves, May 1993.</i>	Not tested	Pass

8. [807.92(a)(c)] **Non-clinical performance data:**

A summary of results of non-clinical performance evaluations is presented above. A brief description of these tests follows:

A: Dimensional and Physical Properties.

ASTM D3578-91 specifies the dimensional measurement requirements including thickness to which the Applicant and K932404 gloves comply, unless otherwise noted.

1,000 mL FDA Water Leak Test consists of attaching a glove over the end of a plastic cylinder and dispensing 1,000 mL of water into the glove. Leaks within a two-minute period are recorded as failures. Testing is performed according to 21CFR 800.20 (b)(1). Sampling is performed utilizing Mil Std. 105E or an increased sampling tightness when deemed appropriate. Applicant glove and K932404 meet this FDA requirement.

B: The powder-free test method is an assay, described as recommendations in the Regulatory Requirements for Medical gloves by the Division of Small Manufacturers Assistance, CDRH, FDA May, 1993. A water extract of the gloves is filtered, dried and the residue weighed to determine the total particulate removed from the glove. Applicant glove and K932404 demonstrate very low particulate/cornstarch levels; however, no standards have been set by the FDA or the ASTM.

C: Biocompatibility.

Primary Dermal Irritation. The testing is performed according to the regulations of the Consumer Product Safety Commission, Title 16, Chapter II, Part 1500. The purpose of the study is to determine the dermal irritation potential of the glove to the shaved intact and abraded skin on the backs of albino rabbits. Appropriate controls were conducted. Applicant glove showed no significant irritancy potential.

Dermal Sensitization (Buehler) Study. This study is performed on fifteen young adult Hartley Guinea Pigs (male) per extract to determine the sensitization potential of the gloves. Safeskin Powder-Free Nitrile Exam Gloves were tested with Dinitrochlorobenzene (DCNB) used for a positive control substance. A one inch square patch of test material was applied to clipped areas of the test animals, once weekly for three weeks, six hours per exposure. Erythema and edema were scored according to Draize evaluation. The Challenge phase was conducted two weeks after the last administration of induction dose in the same manner as previously described. Appropriate controls were conducted. Applicant glove showed no significant sensitization potential.

9. [807.92(b)(2)]

Clinical Performance Data:

The 200 person Modified Draize Test was performed on the applicant glove to comply with FDA requirements for obtaining the Hypoallergenic claim. This test was conducted to determine by epidermal contact the primary or cumulative irritation and/or sensitization potential of the test material. Test site was the upper back between the scapulae. Test sample portions of the glove were attached to the back. This procedure was followed three times per week for a total of ten applications. Observations and scoring were made at each test period. Following a two-week rest period, two consecutive challenge patches of the test material were applied to a different site on the scapular back under occlusive patches.

10. [807.92 (b)(3)] **Conclusions drawn from the non-clinical and clinical tests in 7, 8, and 9 above:**
The applicant glove meets or exceeds ASTM standards, FDA pinhole requirements and labeling claims as demonstrated in 7, 8, and 9 above.
11. [807.92 (d)] **Other information deemed necessary by the FDA.**
No other information has been requested at this time.