MAR - 2 2000

K993117

September 1, 1999

[1] 510(k) Summary of Safety and Effectiveness Information

[2] Safeskin Corporation
12671 High Bluff Drive
San Diego, CA 92130

Telephone: 619-794-8111
Fax: 619-350-2382

Contact: Eugene V. Goorchenko
Telephone: 619-509-7010
Fax: 619-350-2382

[3] Trade Names: "Safeskin PFE-XTRA Latex Examination Glove"
Common Name: Patient Examination Glove
Classification Name: Patient Examination Glove

[4] The predicate is a Safeskin powder free examination glove which meets all of the requirements of ASTM D 3578-00, Standard Specification for Rubber Examination Gloves for Medical Application.

[5] The Safeskin PFE-XTRA Examination Glove will meet all the current specifications for ASTM D 3578-99.

[6] The Safeskin PFE-XTRA Examination Glove is a disposable device intended to be worn by healthcare and similar personnel to prevent contamination between such personnel and the patient and for use with chemotherapeutic agents.

[7] The Safeskin PFE-XTRA Examination Glove posesses the following technological characteristics (as compared to ASTM or equivalent standards):

Characteristics	Standards
Dimensions	Meets ASTM D 3578-99
Physical Properties	Meets ASTM D 3578-99
Freedom from pinholes	Meets ASTM D 3578-99 Meets ASTM D 5151
Powder-Free	Meets ASTM D 6124 4 mg/glove maximum

Biocompatability

Primary Skin Irritation in Rabbits	Passes
Guinea Pig Sensitization	Passes

[8] The performance test data that support a determination of substantial equivalence are described above.

[9] Clinical data are not needed for examination gloves.

[10] It can be concluded that the Safeskin PFE-XTRA Examination Glove is safe and effective for use with chemotherapeutic agents and will perform according to the glove performance standards referenced in Section 7 above, thereby meeting ASTM standards, FDA requirements, and the labeling claims for the product. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2000

Mr. Eugene V. Goorchenko
Director of Regulatory Affairs
Safeskin Corporation
12671 High Bluff Drive
San Diego, California 92130

Re: K993117
Trade Name: Safeskin Pfe-xtra® Latex Examination Glove with Protein Labeling Claim (50 microgram or less)
Regulatory Class: I
Product Code: LYY
Dated: December 29, 1999
Received: December 30, 1999

Dear Mr. Goorchenko:

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

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) 594-4690. 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

INDICATIONS FOR USE

Applicant: Safeskin Corporation

510(k) Number (if known): K993117

Device Name: ~~Safeskin PFE-XTRA Powder-Free Latex Examination~~ Glove with Protein Claim 50 mcg or less

Indications For Use:

A medical examination glove intended to be worn on the hands of healthcare personnel and similar personnel to prevent contamination between such personnel and the patient and for use with chemotherapeutic agents.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993117

(Optional Format 1-2-96)