



MAY 21 1999

K991317

SAFESKIN

SAFESKIN CORPORATION
12671 HIGH BLUFF DRIVE
SAN DIEGO, CALIFORNIA 92130
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April 16, 1999

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

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

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

[3] Trade Name: Safeskin® PFS PLUS powder-free latex surgical gloves, *polymer coated*
Common Name: Surgical Gloves *contains 50 mcgm or less of total*
Classification Name: Surgeon's Gloves *water extractable protein per gram*

[4] The predicate is a Safeskin® powder-free latex surgical glove which meets all of the requirements of ASTM D 3577.

[5] The Safeskin® PFS Plus powder-free latex surgical glove will meet all the current specifications for ASTM D 3577, rubber surgical gloves.

[6] Safeskin® PFS Plus powder-free latex surgical gloves are sterile disposable devices intended to be worn by operating room personnel to prevent contamination between such personnel and the patient during a surgical procedure.

[7] Safeskin® PFS Plus powder-free latex surgical gloves possess the following technological characteristics (as compared to ASTM or equivalent standards):

Characteristics	Standards
Dimensions	Meets ASTM D 3577

Physical Properties Meets ASTM D 3577

Freedom from pinholes Meets ASTM D 3577
Meets ASTM D 5151

Powder-Free Meets ASTM D 6124
Less than 2 mg/glove

Biocompatibility
Primary Skin Irritation in Rabbits Passes
Guinea Pit Sensitization Passes

- [8] The performance test data that support a determination of substantial equivalence are described above.
- [9] Clinical data are not needed for surgical gloves.
- [10] It can be concluded that the Safeskin® PFS Plus powder-free latex surgical glove will perform according to the glove performance standards referenced in Section 7 above and therefore will meet ASTM standards, FDA requirements, and the labeling claims for the product. Consequently, this device is substantially equivalent to currently marketed devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991317

Trade Name: Safeskin® PFS PLUS powder-free latex
surgeon's glove ,contains 50 mcgm or less of total
water extractable protein per gram

Regulatory Class: I

Product Code: KGO

Dated: April 16, 1999

Received: April 19, 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 (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.

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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,


for 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: K991317

Device Name: Surgeon's glove PFS PLUS, Powder-Free Polymer Coated
50mgm or less of Total water extractable Protein per gm

Indications for Use:

A surgeon's glove is intended to be worn on the hands of operating room personnel to prevent contamination between such personnel and the patient during a surgical procedure.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Over-The-Counter X



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices