Kimberly-Clark

K012815

NOV 13 2001

August 21, 2001

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

[2] Kimberly-Clark Corporation
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Contact: Marcia Johnson
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[3] Trade Name: "SAFESKIN HEALTHTOUCH" Powder-Free Latex Exam Glove with Vitamin E and Aloe
Common Name: Patient Examination Gloves, Latex
Classification Name: Patient Examination Gloves, Latex

[4] The predicate device is a Class I, powder-free latex exam glove 80LYY that meets all of the requirements of ASTM D 3578-00a, Standard Specification for Rubber Examination Gloves.

[5] The powder-free latex exam glove with vitamin E and aloe meets the current specifications for ASTM D 3578-00a.

[6] The powder-free latex exam gloves with vitamin E and aloe are disposable devices intended to be worn by healthcare and similar personnel to prevent contamination between such personnel and the patient.

[7] The powder-free latex exam gloves with vitamin E and aloe possess the following technological characteristics (as compared to ASTM or equivalent standards):

Characteristics	Standards
Dimensions	Meets ASTM D 3578-00a
Physical Properties	Meets ASTM D 3578-00a
Freedom from pinholes	Meets ASTM D 3578-00a Meets ASTM D 5151-99
Powder Free	Meets ASTM D 6124-00a Meets ASTM D 3578-00a

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Protein Content	Meets ASTM D 5712-99 < 50 µg/g

Biocompatability

Primary Skin Irritation in Rabbits	Passed
Guinea Pig Sensitization	Passed

[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 powder-free latex exam glove with vitamin E and aloe is safe and effective 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 exam glove is substantially equivalent to currently marketed exam gloves.

Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, Georgia 30076 (770) 587-8000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2001

Ms. Marcia Jonhson
Senior Regulatory Associate
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K012815
Trade/Device Name: Safeskin Healthtouch Powder-Free Examination Glove with Vitamin E, Aloe and Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 21, 2001
Received: August 22, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/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

NOV 1 3 2001

INDICATIONS FOR USE

Applicant: Kimberly-Clark Corporation

510(k) Number: K012815

Device Names: SAFESKIN HEALTHTOUCH Powder-Free Latex Exam Glove with Vitamin E and Aloe with Protein Labeling Claim (50 MICROGRAMS OR LES

Indications for Use:

A medical glove intended to be worn on the hands of healthcare and similar personnel to prevent contamination between such personnel and the patient.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Over-The-Counter _____

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012815

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