Encore Mark IV Powder Free Surgical Gloves
Ansell Perry
1875 Harsh Avenue SE
Massillon, Ohio 44646
Telephone: 330-833-2811
Fax: 330-833-6213

FEB - 9 1998

K974783

Checklist
Section 21.0

[1] 510 (k) Summary

[2] Ansell Perry Inc.
1875 Harsh Avenue SE
Massillon, Ohio 44646

Telephone: 330-833-2811
Fax: 330-833-6213

Contact: James R. Chatterton
Telephone: 330-833-2811
Fax: 330-833-6213

December 18, 1997

[3] Trade Name: Encore Mark IV Powder Free Surgical Gloves
Common Name: Surgical Gloves
Classification Name: Surgeon's Glove

[4] Encore Mark IV Powder Free Surgical Gloves, meet all of the requirements of ASTM D 3577, Type 1.

[5] Encore Mark IV Powder Free Surgical Gloves meet all the current specifications for ASTM D 3577 Rubber Surgical Gloves.

[6] Encore Mark IV Powder Free Surgical Gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

[7] Encore Mark IV Powder Free Surgical Gloves are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standard
Dimensions	Meets ASTM D 3577
Physical Properties	Meets ASTM D 3577, Type 1

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Freedom from holes	Meets ASTM D 3577 Meets ASTM D 5151
Powder-Free	Meets ASTM D 6124
Meets described test in Attachment VI	Not more than 2 mg residue by mass.
Biocompatability	
Primary Skin Irritation in Rabbits	Passes
Guinea Pig Sensitization	Passes

[8] The performance test data of the non clinical tests are the same as mentioned immediately above.

[9] Clinical data is not needed for medical gloves or for most devices cleared by the 510(k) process.

[10] It is concluded that Encore Mark IV Powder Free Surgical Gloves are as safe, as effective, and perform as well as the glove performance standards referenced in Section 7 above and therefore meet:

ASTM listed standards,
FDA hole requirements, and
labeling claims for the product.

[11] This summary will include any other information reasonably deemed necessary by The FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB -9 1998

Mr. James R. Chatterton
Vice President Regulatory Affairs/Technical
Ansell Perry
1875 Harsh Avenue, S.E.
Massillon, Ohio 44646-7199

Re: K974783
Trade Name: Encore Mark IV Powder Free Latex Surgical Gloves, Polymer Coated
Regulatory Class: I
Product Code: KGO
Dated: December 18, 1997
Received: December 22, 1997

Dear Mr. Chatterton:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 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) 594-4618. 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" (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

3.0 Indications for Use Statement:

INDICATIONS FOR USE

Applicant: Ansell Perry

510(K) Number (if known): K974783 *

Device Name: Surgeons Glove, latex polymer coated, powder free

Indications For Use:

A device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of **Dental, Infection Control,**
and General **Hospital Devices**
510(k) Number K974783

Prescription Use _____ OR Over-The-Counter X
Per 21 CFR 801.109