

K983489

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

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

September 30, 1998

[3] Trade Name: Encore Mark IV Powder Free Surgical Gloves (Protein Labeling Claim)  
Common Name: Surgical Gloves  
Classification Name: Surgeon's Glove

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

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

[6] Encore Mark IV Powder Free Surgical Gloves (Protein Labeling Claim) 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 (Protein Labeling Claim) 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 described test in Attachment VI	Meets ASTM D 6124 Not more than 2 mg residue by mass.
Protein Label Claim	This latex glove contains 50 micrograms or less of total water extractable protein per gram.
Biocompatibility Primary Skin Irritation in Rabbits Guinea Pig Sensitization	Passes 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 (Protein Labeling Claim) 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.



DEC 14 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K983489  
Trade Name: Encore Mark IV Powder-Free Polymer Coated  
Latex Surgical Glove with Protein Content Labeling  
Claim (50 Micrograms or Less)  
Regulatory Class: I  
Product Code: KGO  
Dated: September 30, 1998  
Received: October 5, 1998

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 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). 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 Current Good Manufacturing Practice requirements, 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 pre-market notification submission does not affect any obligation you might have under sections 531

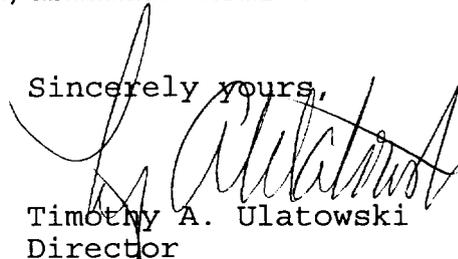
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21CFR 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/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

3.0 Indications for Use Statement:

INDICATIONS FOR USE

Applicant: Ansell Perry

510(K) Number (if known): K983489 \*

Device Name: Surgeons Glove, latex polymer coated, powder free with protein label claim (50 MICROGRAM OR LESS)

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 K983489

Prescription Use \_\_\_\_\_  
21 CFR 801.109

OR

Over-The-Counter X

(Optional Format 1-2-96)