

MAY 11 1998

K981392

Elite™ Powder Free Polyurethane Synthetic Surgical Gloves  
 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 10, 1997

[3] Trade Name: Elite™ Powder Free Polyurethane Synthetic Surgical Gloves  
 Common Name: Surgical Gloves, Green Polyurethane  
 Classification Name: Surgeon's Glove

[4] Elite™ Powder Free Polyurethane Synthetic Surgical Gloves, meet all of the requirements of ASTM D 3577, Type 2.

[5] Elite™ Powder Free Polyurethane Synthetic Surgical Gloves meet all the current specifications for ASTM D 3577 Rubber Surgical Gloves.

[6] Elite™ Powder Free Polyurethane Synthetic Surgical Gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

[7] Elite™ Powder Free Polyurethane Synthetic 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 2



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K981392  
Trade Name: Elite Mark IV Sterile Powder-Free  
Polyurethane Synthetic Surgical Gloves (Green)  
Regulatory Class: I  
Product Code: KGO  
Dated: April 9, 1998  
Received: April 17, 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 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 obligation you might have under sections 531 through 542 of

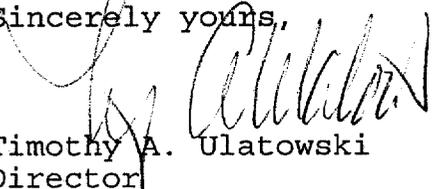
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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,



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):     K981392    \*

Device Name:     Surgeon's Glove, powder free, polyurethane, green color    

**Indications For Use:**

A device made of synthetic 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)

(Division Chief) *George A. Miller for Chin S. Lin PhD*  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number     K981392    

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

OR

Over-The-Counter \_\_\_\_\_