

DEC 18 1997

DermaClean Sterile (Protein Labeling Claim)  
Ansell Perry  
1875 Harsh Avenue SE  
Massillon, Ohio 44646  
Telephone: 330-833-2811  
Fax: 330-833-6213

Checklist  
Section 21.0

K974218

[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

October 28, 1997

[3] Trade Name: DermaClean Sterile (Protein Labeling Claim)  
Common Name: Examination Gloves  
Classification Name: Patient Examination Glove

[4] DermaClean Sterile (Protein Labeling Claim) examination gloves, meet all of the requirements of ASTM D 3578.

[5] DermaClean Sterile (Protein Labeling Claim) examination gloves meet all the current specifications for ASTM D 3578 Rubber Examination Gloves.

[6] DermaClean Sterile (Protein Labeling Claim) examination gloves are disposable device intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

[7] DermaClean Sterile (Protein Labeling Claim) examination gloves are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standard
Dimensions	Meets ASTM D 3578
Physical Properties	Meets ASTM D 3578

**DermaClean Sterile (Protein Labeling Claim)**

**Ansell Perry**  
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Massillon, Ohio 44646  
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**Freedom from holes**

**Meets ASTM D 3578**  
**Meets ASTM D 5151**

**Powder-Free**

**Not more than 2 mg residue by mass.**

**Meets described test in Attachment VI**

**Protein Label Claim**

**This latex glove contains 50 micrograms or less of total water extractable protein per gram.**

**Biocompatibility**

**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 DermaClean Sterile (Protein Labeling Claim) examination 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

DEC 18 1997

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

Re: K974218  
Trade Name: Dermaclean Sterile Latex Examination Gloves  
with Protein Label Claim (50 micrograms or less of  
total water extractables protein per gram.)  
Regulatory Class: I  
Product Code: LYY  
Dated: October 28, 1997  
Received: November 10, 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 (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 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 pre-market notification submission does

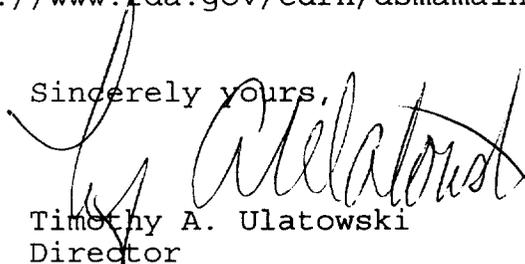
Page 2 - Mr. Chatterton

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 Inc.

510(K) Number (if known): K974218

Device Name: Latex Patient Examination Glove Sterile, Powder Free with Protein Label Claim (50 micrograms or less of total water extractables protein per gram.)

Indications For Use:

A disposable device intended for medical purpose that is worn on the examiners hand to prevent contamination between patient and examiner.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

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

510(k) Number K974218

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

OR

Over-The-Counter Y

(Optional Format 1-2-96)