Ansell

JAN 1 9 2005

K043508

[1] 510(k) SUMMARY
Derma Prene® Ultra Powder-Free Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use)

[2] Ansell Healthcare Products LLC
1635 Industrial Road
Dothan, AL 36303

Contact: Lon D. McIlvain, Vice President Regulatory Affairs
Telephone: (334) 615-2562
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December 17, 2004

[3] Trade Name: Derma Prene® Ultra Powder-Free Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use)
Common Name: Surgical Gloves
Classification Name: Surgeon's Glove

[4] Derma Prene® Ultra Powder-Free Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use) meet all of the requirements of ASTM D 3577, Type 2.

[5] Derma Prene® Ultra Powder-Free Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use) meet all of the current specifications of ASTM D 3577, Type 2.

[6] Derma Prene® Ultra Powder-Free Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use) are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination and for use handling chemotherapy drugs.

[7] Derma Prene® Ultra Powder-Free Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use) 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
Freedom from Holes	Meets ASTM D 3577 Meets ASTM D 5151
Powder-Free	Meets ASTM D 6124 Powder content $\leq$ 2 mg per glove
Biocompatibility	
Primary Skin Irritation in Rabbits	Passes
Guinea Pig Sensitization	Passes
Cytotoxicity Study using the End-Point Titration Method	Non-Toxic at 24 hours

[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 Derma Prene® Ultra Powder-Free Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use) 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

JAN 19 2005

Mr. Lon D. McIlvain
Vice President Regulatory Affairs
Ansell Healthcare Products LLC
1635 Industrial Road
Dothan, Alabama 36303

Re: K043508
Trade/Device Name: Derma Prene® Ultra Powder-Free Green Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use)
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: December 17, 2004
Received: December 20, 2004

Dear Mr. McIlvain:

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.

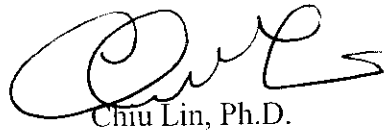
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)

K043508

Device Name

Derma Prene® Ultra Powder-Free Green Polychloroprene Synthetic Surgical Gloves (Chemotherapy Use)

Indications for Use

A device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination and for use handling chemotherapy drugs.

Prescription Use _____ (Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K043508