K013604

Ansell

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NOV 1 3 2001

Ultralon® Powder Free Latex Surgical Gloves (Protein Label Claim)

[1] **510(k) Summary**

[2]	Submitter:	Ansell Healthcare Products Inc. Inc. 1875 Harsh Avenue SE Massillon, Ohio 44646
	Contact:	James R. Chatterton
	Telephone:	330-833-2811 x297
	Fax:	330-833-6501
	Date of Preparation:	October 16, 2001
[3]	Trade Name:	Ultralon® Powder Free Latex Surgical Gloves
	Common Name:	Surgical Gloves
	Classification Name:	Surgeon's Glove
[4]	Legally Marketed Device to Which Equivalency Is Being Claimed:	Ultralon® Powder Free Latex Surgical Gloves, cleared for the market under 510(k) K973699, December 16, 1997
[5]	Device Description:	Ultralon® Powder Free Latex Surgical Gloves (Protein Label Claim) meet all the current specifications for ASTM D 3577-00, Rubber Surgical Gloves, Type 1.
[6]	Intended Use:	Ultralon® Powder Free Latex Surgical Gloves (Protein Label Claim) are sterile disposable devices intended to be worn by operating room personnel to protect surgical wounds from contamination.

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[7] Summary of Technological Characteristics Compared to Predicate Device

Ultralon® Powder Free Latex Surgical Gloves (Protein Label Claim) are equivalent to the predicate device in that they have the same following technological characteristics.

Characteristic	Standard
Dimensions	Meets ASTM D 3577-00
Physical Properties	Meets ASTM D 3577-00
Freedom from holes	Meets ASTM D 3577-00
	Meets ASTM D 5151-99
Biocompatability	Passes Primary Skin Irritation in Rabbits Test
	Passes Guinea Pig Sensitization Test

Ultralon® Powder Free Latex Surgical Gloves (Protein Label Claim) have the additional characteristic:

Protein Label Claim: This latex glove contains 50 micrograms or less of total water extractable protein per gram	Meets ASTM D 5712-99 Standard Test Method for Analysis of Protein in Natural Rubber and Its Products

[8] Brief Discussion of Non-clinical Tests

Non-clinical test data (see [7] above) indicate that the product meets all applicable ASTM standards, and FDA requirements for biocompatibility and protein label claim.

[9] Clinical Tests:

Clinical data are not needed for medical gloves or for most devices cleared by the 510(k) process.

[10] Conclusions Drawn from Non-clinical Tests:

It is concluded that the Ultralon® Powder Free Latex Surgical Gloves (Protein Label Claim) are as safe and effective, and perform as well as the predicate product. They meet ASTM listed standards, and FDA requirements for holes and protein labeling claims.

[11] Other Information Deemed Necessary by FDA

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

NOV 1 3 2001

Mr. James R. Chatterton
Vice President Regulatory
Ansell Healthcare Products, Incorporated
1875 Harsh Avenue, SE
Massillon, Ohio 44646

Re: K013604
Trade/Device Name: Ultralon ® Powder Free Latex Surgical Gloves with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove, Powder-Free
Regulatory Class: I
Product Code: KGO
Dated: October 15, 2001
Received: October 31, 2001

Dear Mr. Chatterton:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

NOV 1 3 2001

510(k) Number (if known) K013604

Device Name Ultralon® Powder Free Surgical Gloves WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)

Indications for Use Ultralon® Powder Free Latex Surgical Gloves are 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)

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013604