Ansell Edmont
Industrial

K982131

Ansell Edmont Industrial Inc.

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OCT 29 1998

Nitra-Touch™
Ansell Edmont Industrial, Inc.
1300 Walnut Street
Coshocton, Ohio 43812
Telephone: 740-622-4311
Fax: 740-623-3515

Checklist
Section 21.0

[1] 510 (k) Summary

[2] Ansell Edmont Industrial, Inc.
1300 Walnut Street
Coshocton, Ohio 43812

Telephone: 740-622-4311
Fax: 740-623-3515

Contact: Mike W. Hagans
Telephone: 740-623-3595
Fax: 740-623-3515

June 12, 1998

[3] Trade Name: Nitra-Touch™
Common Name: Exam Gloves
Classification Name: Patient Examination Glove

[4] Nitra-Touch™ examination gloves, meet all of the requirements of ASTM D 3578 with the following variation.

[5] Nitra-Touch™ examination gloves meet all the current specifications for ASTM D 3578 Rubber Examination Gloves except for the ultimate elongation percentage before and after aging.

[6] Nitra-Touch™ examination gloves are disposable device intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner and for use handling chemotherapy drugs.

[7] Nitra-Touch™ 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

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Except Ultimate Elongation meets specifications described under Attachment II	Original Ultimate Elongation 500% minimum Aged Ultimate Elongation 400% minimum
Freedom from holes Meets ASTM D 5151	Meets ASTM D 3578
Powder-Free Meets described test in Attachment V	Not more than 2 mg residue by mass.
<u>Tensile Strength MPa</u> Tensile Strength 60% higher than vinyl (synthetic) examination gloves Vinyl = 10.5 Nitra-Touch™ = 17.1	ASTM D 5250 ASTM D 3578
<u>Puncture lbf/in</u> Puncture resistance of Nitra-Touch™ is eight (8) times greater than vinyl and nearly twice that of competitive nitrile gloves	ASTM D 120-87 Nitra-Touch™ = 1625 Blue Nitrile = 929 Vinyl (Synthetic) = 184
<u>Glutaraldehyde Resistance</u> Nitrile film provides excellent chemical resistance to glutaraldehyde.	ASTM T F739-91 Source: TRI/Environmental, Inc. Breakthrough Time = >480
Permeation Rate = <0.013 Fg/cm^{2*} min	
Biocompatability 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 Nitra-Touch™ 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

OCT 29 1998

Mr. Mike W. Hagans
Ansell Edmont Industrial, Incorporated
1300 Walnut Street
Coshocton, Ohio 43812

Re: K982131
Trade Name: Nitra-Touch™ Powder-Free Nitrile Medical Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: September 9, 1998
Received: September 21, 1998

Dear Mr. Hagans:

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 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 Edmont Industrial, Inc.

510(K) Number (if known): K982131 *

Device Name: ~~Patient Examination Glove~~ NITRA TOUCH POWDER-FREE NITRILE MEDICAL EXAMINATION GLOVE

Indications For Use:

A disposable device intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner and for use handling chemotherapy drugs.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K982131

scription Use _____ OR Over-The-Counter X
r 21 CFR 801.109

(Optional Format 1-2-96)