K092327

Ansell

SEP 21 2009

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Dothan, AL 36303
Tel: (334) 615-2563
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510(k) SUMMARY

1.0 Submitter:

Ansell Healthcare Products LLC
1635 Industrial Road
Dothan, AL 36303

2.0 Contact Information:

Cynthia A. Ingram, Regulatory Affairs Manager, Americas
Telephone: (334) 615-2563
Fax: (334) 615-2568

3.0 Name of Device:

Trade Name: Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination Gloves (Chemotherapy Use)

Common Name: Patient Examination Gloves

Classification Name: Glove, Patient Examination, Nitrile

4.0 Identification of the Device:

Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination Gloves (Chemotherapy Use) meet all of the requirements of ASTM D 6319-00a(2005).

5.0 Description of the Device:

Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination Gloves (Chemotherapy Use) meet all of the current specifications of ASTM D6319-00a(2005), Standard Specification for Nitrile Examination Gloves for Medical Application.

6.0 Intended Use of the Device:

Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination Gloves (Chemotherapy Use) are non-sterile disposable devices to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body, fluids, waste or environment and for use in handling chemotherapy drugs.

7.0 Summary of Technological Characteristics of the Device:

Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination Gloves (Chemotherapy Use) are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standard	Device Performance
Dimensions	ASTM D 6319-00a(2005)	Meets
Physical Properties	ASTM D 6319-00a(2005)	Meets
Freedom from Holes	ASTM D 6319-00a(2005) ASTM D 5151-06	Meets
Powder-Free	ASTM D 6124-06	≤ 2 mg per glove
Biocompatibility	ISO Skin Irritation Study ISO Maximization Sensitization Study – Extract Cytotoxicity Study Using the End-Point Titration Method	Passes Passes Non-toxic at 24 hours for dilutions 1:2 through 1:32
Chemotherapy Drug Permeation Test	ASTM D 6978-05	Chemotherapy Drug Permeation (average breakthrough time in minutes) Carmustine 45.27 Cyclophosphamide >240 Doxorubicin Hydrochloride >240 Etoposide (Toposar) >240 5-Fluorouracil >240 Paclitaxel (Toxol) >240 Thio-Tepa 93.50 Vincristine Sulfate >240 Methotrexate >240

8.0 Substantial Equivalence Based on Assessment of Non-Clinical Performance Data:

The performance test data of the non-clinical tests are the same as mentioned immediately above.

9.0 Substantial Equivalence Based on Assessment of Clinical Performance Data:

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

10.0 Conclusion:

It is concluded that Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination 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.

This device is substantially equivalent to currently marketed devices.

This summary will include any other information reasonably deemed necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2009

Ansell Healthcare Products LLC
C/O Mr. Casey Conry
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

Re: K092327
Trade/Device Name: Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination Gloves, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: September 4, 2009
Received: September 8, 2009

Dear Mr. Conry:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement:

INDICATIONS FOR USE

510(K) Number (if known): K092327

Device Name: Micro-Touch® NitraFree™ Nitrile Powder-Free Pink Examination Gloves, Tested for Use with Chemotherapy Drugs

Indications For Use:

This is a medical glove to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body, fluids, waste or environment, and tested for use with chemotherapy drugs.

Chemotherapy Drug Permeation
(average breakthrough detection time in minutes) (ASTM D6978-05)

*Carmustine	45.27
Cyclophosphamide	>240
Doxorubicin Hydrochloride	>240
Etoposide (Toposar)	>240
5-Fluorouracil	>240
Paclitaxel (Toxol)	>240
Thio-Tepa	93.50
Vincristine Sulfate	>240
Methotrexate	>240

***Caution: Testing showed an average breakthrough time of 45 minutes with Carmustine.**

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (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: K092327