K103714

Ansell

JUL - 7 2011

1635 Industrial Road
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: 334-615-2573

3.0 Name of Device:

Trade Name: Encore® Acclaim® Sterile Powder-Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim <50µg/dm^2 per Glove of Extractable Protein

Common Name: Surgeon's Gloves

Classification Name: Surgeon's Gloves

4.0 Legally Marketed Devices to Which Equivalence is being Claimed:

Device Name: Encore Mark IV Powder-Free Surgical Gloves
510(k) Number: K983489

Device Name: Duraprene Sterile Synthetic Powder-Free Surgical Gloves with Tested for use with Chemotherapy Drugs Labeling Claim
510(k) Number: K013302

5.0 Identification of the Device:
Encore® Acclaim® Sterile Powder-Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim <50µg/dm^2 per Glove of Extractable Protein.

6.0 Description of the Device:
The Encore Acclaim Sterile Powder-Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim <50µg/dm^2 per Glove of Extractable Protein, is a disposable device made of natural latex rubber that is intended to be worn by operating room personnel to protect a surgical wound from contamination, and is tested for use with chemotherapy drugs.

7.0 Intended Use of the Device:
A device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The device has been tested for use with chemotherapy drugs.

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

Vincristine Sulfate (1.0mg/mL)	>240
Carmustine (BiCNU)(3.3mg/mL)	1.5
Cyclophosphamide (Cytoxan)(20.0mg/mL)	>240
Doxorubicin Hydrochloride (2.0mg/mL)	>240
5-Fluorouracil (50.0mg/mL)	>240
Methotrexate (25.0mg/mL)	>240
Etoposide (Toposar)(20.0mg/mL)	>240
Paclitaxel (Toxol)(6.0mg/mL)	>240
ThioTEPA (10.0mg/mL)	15.26

Please note that Carmustine and ThioTEPA have extremely low permeation times of 1.5 and 15.26 minutes respectively.

8.0 Summary of Technological Characteristics of the Device:

Encore Acclaim Sterile Powder-Free Latex Surgical Gloves , Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim <50µg/dm^2 per Glove of Extractable Protein have the following technological characteristics compared to ASTM or equivalent standards:

Characteristics	**Standard**	**Device Performance**
Dimensions	ASTM D3577-09e1	Meets
Physical Properties	ASTM D3577-09e1	Meets
Freedom from Holes	ASTM D3577-09e1 ASTM D 5151-06	Meets
Powder-Free	ASTM D 6124-06	≤ 2 mg per glove
Protein Content	ASTM D3577-09e1 ASTM D 5712	Maximum 50 µg/dm^2
Biocompatibility	Dermal Sensitization Primary Skin Irritation Study	Passes Passes

9.0 Substantial Equivalence Based on Assessment of Non-Clinical Performance Data:
The subject device is substantially equivalent to the predicate devices based on an assessment of the non-clinical performance data.

10.0 Substantial Equivalence Based on an Assessment of Clinical Performance Data:
A clinical study was not conducted on the subject or predicate devices.

11.0 Conclusion:
The Encore Acclaim Sterile Powder-Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim <50µg/dm^2 per Glove of Extractable Protein is as safe and effective as the predicate devices. The subject device has been tested against the ASTM standards listed above and met the requirements of those standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Cynthia A. Ingram
Regulatory Affairs Manager, Americas
Ansell Healthcare Products, LLC
1635 Industrial Road
Dothan, Alabama 36303

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Re: K103714
Trade/Device Name: Encore Acclaim Sterile Powder-Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim >50µg/dm^2 Per Glove of Extractable Protein
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO, LZC
Dated: June 16, 2011
Received: June 17, 2011

Dear Ms. Ingram:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Enclosure

K103714

3.0 Indications for Use Statement:

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Encore Acclaim Sterile Powder-Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim <50µg/dm^2 per Glove of Extractable Protein

Indications For Use:

A device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The device has been tested for use with chemotherapy drugs.

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

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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)

Philip Pangulinan, Ph.D. 7/6/2011
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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