SEP - 2 2011

K111139

Ansell

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Dothan, AL 36303
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510(k) SUMMARY

1.0 Submitter: Ansell Healthcare Products LLC
1635 Industrial Road
Dothan, AL 36303

2.0 Date of Preparation: July 21, 2011

3.0 Contact Information: Cynthia A. Ingram, Regulatory Affairs Manager, Americas
Telephone: 334-615-2563 Fax: 334-615-2573

4.0 Name of Device:
Trade Name: Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs

Common Name: Surgeon's Gloves
Classification Name: Surgeon's Gloves

5.0 Legally Marketed Device to Which Equivalence is being Claimed:

Device Name:
Cardinal Health Duraprene SMT Powder-Free Synthetic Neoprene Surgical Gloves Tested for Use with Chemotherapy Drugs

510(k) Number:
K013302

6.0 Identification of the Device:

Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs

7.0 Description of the Device:
The Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs, is a disposable device made of synthetic 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. A coating of Aliphatic Polyester Polyurethane is applied to the inner surface of the glove to make donning easy.

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8.0 Intended Use of the Device:

These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs.

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

*Carmustine	15.5
Cyclophosphamide	>240
Doxorubicin Hydrochloride	>240
Etoposide (Toposar)	>240
5-Fluorouracil	>240
Paclitaxel (Toxol)	>240
*ThioTEPA	15.5
Methotrexate	>240
Vincristine Sulfate	>240

Please note that Carmustine and ThioTEPA have an extremely low permeation time of 15.5 minutes.

9.0 Summary of Technological Characteristics of the Device:

Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs 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

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

Comparison to Predicate – The subject device (Derma Prené® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs) compares favorably to the predicate device (Cardinal Health Duraprene SMT Powder-Free Synthetic Neoprene Surgical Gloves Tested for Use with Chemotherapy Drugs) as indicated in the tabulated summary below.

Substantial Equivalence Comparison Table

	Subject Device ***Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs***	**Predicate Device** ***Cardinal Health Duraprene SMT Gloves, Tested for Use with Chemotherapy Drugs*** **(Allegiance Healthcare Corporation K013302)**	**Substantial Equivalence (SE)?**
Indications for Use	These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs.	These gloves are intended for use in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive as well as non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound form contamination.	Yes, Substantially Equivalent
Chemotherapy Permeation Standard	Meets ASTM D6978-05	Meets ASTM F739-91	Yes, Substantially Equivalent
Design Specifications	Meets ASTM D3577-09e1	Meets ASTM D3577 and EN 455-2	Yes, Substantially Equivalent
Performance	Meets ASTM D3577-09e1	Meets ASTM D3577 and EN 455-2	Yes, Substantially Equivalent
Materials	Flexible Synthetic Rubber - Synthetic Polyisoprene Rubber and Aliphatic Polyester Polyurethane inner coating to aid donning	Flexible Synthetic Rubber – Neoprene and Nitrile for easy donning	Yes, Substantially Equivalent
Biocompatibility	Passes	Passes	Yes, Substantially Equivalent
Sterility	Sterile	Sterile	Identical
Color	Synthetic Glove with embedded Colorant –Green	Synthetic Glove with embedded Colorant -Flesh	Yes, Substantially Equivalent
Powder-Free	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Identical

Summary of Differences and Comparison of Safety and Effectiveness – The subject device differs from the predicate in that:

1. The subject device in manufactured from neoprene with the inner surface coated with aliphatic polyester polyurethane donning aid. The predicate device is manufactured from a combination of neoprene and nitrile. Though the materials of construction differ, the subject device's materials are functionally equivalent to those of the cited predicate.

2. Chemotherapeutic agent penetration time testing relevant to the safety of healthcare professionals, with regard to effectiveness of protection from potentially toxic chemicals, was more rigorous for the subject device, and the subject device is therefore substantially equivalent to the predicate.

Non-clinical Comparison to Applicable Standards – The subject device meets the applicable requirements for surgeons gloves with regard to dimensions and sizes, physical properties, freedom from holes, powder residues, and protein content as found in the following standards: ASTM D3577, ASTM D5151, ASTM D6124, and ASTM D5712. The subject device passes biological reactivity testing for dermal sensitization and irritation, in accord with the ISO 10993 series of standards.

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

12.0 Conclusion:
The Encore Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs are as safe and effective as the predicate device. The subject device has been tested against the ASTM standards listed above and met the requirements of those standards. Additional comparisons show the subject device substantially equivalent to the predicate.

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

Ansell Healthcare Products, Incorporated
% Mr. Neil Burris
Regulatory Affairs Consultant
Reglera LLC
555 Zang Street, Suite 100
Lakewood Colorado 80228

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Re: K111139
Trade/Device Name: Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO, LZC
Dated: August 2, 2011
Received: August 4, 2011

Dear Mr. Burris:

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

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

K111139

3.0 Indications for Use Statement:

INDICATIONS FOR USE

510(k) Number (if known): K111139

Device Name: Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs

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Vincristine Sulfate	>240

Please note that Carmustine and ThioTEPA have an extremely low permeation time of 15.5 minutes.

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)

Elizabeth F. Claverie-Wells

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

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