CardinalHealth

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN - 8 2011

STERILE POLYISOPRENE POWDER-FREE SURGICAL GLOVES

(A summary of safety and effectiveness information in accordance with the requirements of 21 CFR 807.92)

Applicant:	Cardinal Health 1430 Waukegan Road McGaw Park, IL 60085
Establishment Registration Number:	1423537
Regulatory Affairs Contact:	Tatyana Bogdan, RAC
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Summary Prepared:	May 13, 2011
Trade Name:	Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs
Common Name:	Surgeon's Gloves
Classification Name:	Surgeon's Gloves
Classification Panel:	General and Plastic Surgery
Regulation:	21 CFR 878.4460
Product Code(s):	KGO
Legally marketed device(s) to which equivalence is claimed:	1. Esteem® SMT Sterile Polyisoprene Powder-Free Surgical Gloves (510(k) K093300, product code KGO) 2. Duraprene Sterile Neoprene Powder-Free Surgical Gloves (510(k) K013302, product code KGO)
Reason for 510(k) Submission:	Addition of new indications for use: Tested for Use with Chemotherapy Drugs
Device Description:	The proposed device is a disposable device. It is not made with natural rubber latex. Instead, it is formulated from polyisoprene, which is a synthetic rubber latex. This Sterile Polyisoprene Powder-Free Surgical Glove is manufactured using exact same material used in the currently cleared device, Esteem SMT glove (K093300) that has been legally marketed by Cardinal Health. The glove is manufactured using molds that feature anti-slip finish, independent thumb, and tapered mechanically locking cuffs to help reduce cuff roll down. It is offered powder-free and sterile.

K110272

Intended Use:

This powder-free surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

	Chemotherapy Drug and Concentration	Min Breakthrough Detection Time, 0.01 $\mu g/cm^2$/minute
1.	Blenoxane (15 mg/ml)	>240
2.	Busulfan (6 mg/ml)	>240
3.	Carmustine (BCNU) (3.3 mg/ml)	**0.37**
4.	Cisplastin, (1.0 mg/ml)	>240
5.	Cytarabine (100 mg/ml)	>240
6.	Cyclophosphamide (20 mg/ml)	>240
7.	Dacarbazine (10 mg/ml)	>240
8.	Doxorubicin HCl (2.0 mg/ml)	>240
9.	Ellence (25 mg/ml)	>240
10.	Etoposide (Toposar) (20 mg/ml)	>240
11.	Fludarabine (25 mg/ml)	>240
12.	Fluorouracil (50 mg/ml)	>240
13.	Idarubicin (1 mg/ml)	>240
14.	Ifosfamide (50 mg/ml)	>240
15.	Mechlorethamine HCl (1 mg/ml)	>240
16.	Melphalan (5 mg/ml)	>240
17.	Methotrexate (25 mg/ml)	>240
18.	Mitoxantrone (2 mg/ml)	>240
19.	Mitomycin C (0.5 mg/ml)	>240
20.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
21.	Paraplatin (10 mg/ml)	>240
22.	Rituximab (10 mg/ml)	>240
23.	Thiotepa (10 mg/ml)	**0.44**
24.	Trisenox (0.1 mg/ml)	>240
25.	Vincristine sulfate (1 mg/ml)	>240

Please note that the following drugs have extremely low permeation time of less than 30 minutes: Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 0.37 minute; Thiotepa (10 mg/ml) has a minimum breakthrough time of 0.44 minute.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	New Device (K110272)	Predicate Sterile Polyisoprene Powder Free Surgical Glove (K093300)	Predicate Sterile Neoprene Powder-Free Surgical Glove (K013302)
Material Composition	Polyisoprene Synthetic Rubber Latex	Polyisoprene Synthetic Rubber Latex	Synthetic Neoprene Polymer coated with Nitrile
Design	Single Use Sterile Powder-free Hand Specific Independent Thumb Beaded Cuff Lubricated	Single Use Sterile Powder-free Hand Specific Independent Thumb Beaded Cuff Lubricated	Single Use Sterile Powder-free Hand Specific Independent Thumb Beaded Cuff Lubricated
Intended Use	Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove
Indications for Use	Tested for Use with Chemotherapy Drugs	Not Tested	Tested for Use with Chemotherapy Drugs
Dimensions & Physical Properties	Meets ASTM D3577	Meets ASTM D3577	Meets ASTM D3577
Freedom from Holes	AQL meets 21CFR 800.20 & ASTM D3577 requirements	AQL meets 21CFR 800.20 & ASTM D3577 requirements	AQL meets 21CFR 800.20 & ASTM D3577 requirements
Powder Residual	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Biocompatibility:		
Primary Skin Irritation	ISO 10993-10	Gloves are non-irritating.
Guinea Pig Maximization	ISO 10993-10	Gloves do not display any potential for sensitization.
Physical Characteristics:		
Dimensions	ASTM D3577	Meet requirements
Physical Properties	ASTM D3577	Meet requirements for rubber surgical gloves
Freedom from Holes	21 CFR 800.20 & ASTM D3577	Tested in accordance with ASTM D5151 with acceptable results
Powder Residual	ASTM D3577 tested using ASTM standard D6124	Gloves meet powder level requirements for "Powder-Free" designation per ASTM D3577. Results generated values < 2mg of residual powder per glove.
Chemotherapy Drug Permeation	ASTM D6978	Gloves were tested using ASTM D6978. Under the test conditions prescribed by the test, the minimum normalized breakthrough detection times for each of the chemotherapy drugs tested exceeded the maximum testing time of

		240 minutes except for Carmustine (BCNU) (3.3 mg/ml) and Thiotepa (10 mg/ml), which showed permeation time of less than 30 minutes.	

Comparative Performance Information Summary

Characteristic	Requirement	New Device	Predicate Device
Biocompatibility:	ISO 10993-1	Meets requirements	Meets requirements
Primary Skin Irritation	ISO 10993-10	Pass	Pass
Guinea Pig Maximization	ISO 10993-10	Pass	Pass
Dimensions	ASTM D3577	Meets requirements	Meets requirements
Physical Properties	ASTM D3577	Meets requirements	Meets requirements
Freedom from Holes	21CFR 800.20 & ASTM D3577	Meets requirements	Meets requirements
Powder Residual	ASTM D3577	Meets requirements	Meets requirements
Chemotherapy Drug Permeation	ASTM D6978	Under the test conditions prescribed by the test, the minimum normalized breakthrough detection times for each of the 25 chemotherapy drugs tested exceeded the maximum testing time of 240 minutes except for Carmustine (BCNU) (3.3 mg/ml) and Thiotepa (10 mg/ml), which showed permeation time of less than 30 minutes.	Duraprene gloves cleared under K013302 were tested with 10 chemotherapy drugs in accordance with and met requirements of ASTM F739 standard. ASTM F739 standard was superseded by ASTM D6978-05. The testing method is the same. The difference is in that the thinnest area of the glove (palm or cuff) is tested and the test results are reported as minimum breakthrough times per ASTM D6978, as opposed to testing a random specimen and reporting the average breakthrough times per ASTM F739.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical data is not required.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

Non-clinical data demonstrates that Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs meet the technological characteristics of ASTM D3577 standard, and are as safe , as effective, and performed as well as the legally marketed devices identified in this summary.

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. Tatyana Bogdan
Regulatory Affairs Manager
Cardinal Health, Incorporated
1430 Waukegan Road
McGaw Park, Illinois 60085

JUN - 8 2011

Re: K110272
Trade/Device Name: Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO, LZC
Dated: May 12, 2011
Received: May 24, 2011

Dear Ms. Bogdan:

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,

for

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

Indications for Use

510(k) Number (if known): K110272

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8.	Doxorubicin HCl (2.0 mg/ml)	>240
9.	Ellence (25 mg/ml)	>240

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claunie-Williams

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

510(k) Number: K110272

(Continued from previous page)

	Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes, 0.01 μg/cm^2/minute
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11.	Fludarabine (25 mg/ml)	>240
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claxton-Williams

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

510(k) Number: K110272

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