DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 23, 2017

WRP Asia Pacific Sdn Bhd
Sarala Jayaraman
Regulatory Affairs Manager
Lot 1, Jalan 3,
Kaw Perusahaan Bandar Baru Salak Tinggi
Sepang, 43900 MY

Re: K161823
Trade/Device Name: Powder Free Nitrile Surgical Glove, Sterile, Tested for use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO, LZC
Dated: December 15, 2016
Received: December 19, 2016

Dear Sarala Jayaraman:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K161823

Device Name
Powder Free Nitrile Surgical Glove, Sterile, Tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*
A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
*Carmustine (BCNU)	3.3mg/ml	30.4
Cisplatin	1.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
Dacarbazine	10.0mg/ml	> 240
Doxorubicin Hydrochloride	2.0mg/ml	> 240
Etoposide (Toposar)	20.0mg/ml	> 240
Fluorouracil	50.0mg/ml	> 240
Ifosfamide	50.0mg/ml	> 240
Mitoxantrone	2.0mg/ml	> 240
Paclitaxel (Taxol)	6.0mg/ml	> 240
*Thiotepa	10.0mg/ml	59.0
Vincristine Sulfate	1.0mg/ml	> 240

CAUTION: Testing showed an average breakthrough time of 30.4 minutes for Carmustine and an average breakthrough time of 59.0 minutes for Thiotepa.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY K161823

1.0 Submitter:

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43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.: +60 3 8706 1486
Fax No.: +60 3 8706 1485

Date of Summary Prepared: 12 January 2017

2.0 Name of the modified device Identification:

Powder Free Nitrile Surgical Glove, Sterile,
Tested for use with Chemotherapy Drugs
510(k) Number: K161823
Common Name: Surgical Gloves
Classification Name: Surgeon's Gloves (21 CFR 878.4460 product code KGO)
Patient Examination Gloves Specialty (21 CFR 880.6250 product code LZC)

3.0 Identification of The Legally Marketed Devices that equivalency is claimed:

	Predicate 1	Predicate 2
Manufacturer	Cardinal Health 200, LLC	Medline Industries, Incorporated
Device name	Cardinal Health™ Sterile Neoprene Powder-free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow)	SensiCare PI Surgical Gloves
510(k) Number	K153316	K152428
Regulatory Class	I	I
Product Code	KGO, LZC	KGO, LZC

4.0 Description of The Device:

Powder Free Nitrile Surgical Glove, Sterile meets all the requirements of ASTM standard D3577-09, D6978-05 and FDA 21 CFR 878.4460.

The powder free nitrile surgical glove is manufactured from synthetic rubber latex. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder on the glove surface. The glove is hand specific. The physical properties of glove i.e. tensile strength meet ASTM standard D3577-09.

510(k) SUMMARY K161823

5.0 Intended Use of the Device:

A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The device has also been tested for use with chemotherapy drugs.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drug	**Concentration**	**Breakthrough Detection Time in Minutes**
*Carmustine (BCNU)	3.3mg/ml	30.4
Cisplatin	1.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
Dacarbazine	10.0mg/ml	> 240
Doxorubicin Hydrochloride	2.0mg/ml	> 240
Etoposide (Toposar)	20.0mg/ml	> 240
Fluorouracil	50.0mg/ml	> 240
Ifosfamide	50.0mg/ml	> 240
Mitoxantrone	2.0mg/ml	> 240
Paclitaxel (Taxol)	6.0mg/ml	> 240
*Thiotepa	10.0mg/ml	59.0
Vincristine Sulfate	1.0mg/ml	> 240

CAUTION: Testing showed an average breakthrough time of 30.4 minutes for Carmustine and an average breakthrough time of 59.0 minutes for Thiotepa.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Surgical Glove, Sterile are summarized with the following technological characteristics compared to ASTM D3577 or equivalent standards as shown in Table 1

Compliant to chemotherapy claim whereby glove thickness and length meets minimal thickness of 0.10 mm and minimal length of 270 respectively.

510(k) SUMMARY K161823

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		
		Predicate 1	**Predicate 2**	**Current**
Manufacturer(s)		Cardinal Health 200, LLC	Medline Industries, Incorporated	WRP Asia Pacific Sdn Bhd
510(k) Number		K153316	K152428	K161823
Intended use	-	A powder-free sterile 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.	The SensiCare PI 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. Warning: Do not use with Carmustine and Thiotepa	A powder-free sterile 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. *CAUTION: Testing showed an average breakthrough time of 30.4 minutes for Carmustine and an average breakthrough time of 59.0 minutes for Thiotepa.
Material	ASTM D3577-09	Synthetic Neoprene Polymer coated with Nitrile	Synthetic Polyisoprene	Nitrile
Color	-	Yellow	Cream colored. Contains a blend of three colorants (naphthos AS red, azo yellow and carbon black)	Natural
Texture	-	-	-	Micro roughened

510(k) SUMMARY K161823

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		
		Predicate 1	**Predicate 2**	**Current**
510(k) Number		K153316	K152428	K161823
Dimensions Length	ASTM D3577-09	Meets Min 270mm	Meets Min 270mm	Meets Min 270mm
Width	ASTM D3577-09	Meets	Meets 5 ½ : 70±6mm 6 : 76±6mm 6 ½ : 83±6mm 7 : 89±6mm 7 ½ : 95±6mm 8 : 102±6mm 8 ½ : 108±6mm 9 : 114±6mm	Meets 5 ½ : 70±6mm 6 : 76±6mm 6 ½ : 83±6mm 7 : 89±6mm 7 ½ : 95±6mm 8 : 102±6mm 8 ½ : 108±6mm 9 : 114±6mm
Thickness - Finger - Palm - Cuff	ASTM D3577-09	Meets	Meets Min 0.10mm Min 0.10mm Min 0.10mm	Meets Min 0.10mm Min 0.10mm Min 0.10mm
Physical Properties Before Aging Tensile Strength : Ultimate Elongation : Stress at 500% Elongation :	ASTM D3577-09	Meets	Meets 7MPa min 650% min 7.0MPa min	Meets 7MPa min 650% min 7.0MPa min
Physical Properties After Aging Tensile Strength : Ultimate Elongation :	ASTM D3577-09	Meets	Meets 12MPa min 490% min	Meets 12MPa min 490% min
Watertight (1000ml)	ASTM D5151-06	Meets 21CFR 800.20 & ASTM D3577 requirements of AQL 1.5	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level 1, AQL 1.5	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level 1, AQL 1.5
Powder Free	ASTM D6124-06 (≤ 2 mg/glove)	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	<2mg of residual powder when tested in accordance with ASTM D3577	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577

510(k) SUMMARY K161823

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		
		Predicate 1	**Predicate 2**	**Current**
510(k) Number		K153316	K152428	K161823
Chemotherapy Drug Permeation Test	ASTM D6978-05			
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
*Carmustine (BCNU)	3.3mg/ml	60.1	10.1	30.4
Cisplatin	1.0mg/ml	> 240	> 240	> 240
Cytarabine	100.0mg/ml	-	> 240	-
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240	> 240	> 240
Dacarbazine	10.0mg/ml	-	> 240	> 240
Doxorubicin Hydrochloride	2.0mg/ml	> 240	> 240	> 240
Etoposide (Toposar)	20.0mg/ml	> 240	> 240	> 240
Fluorouracil	50.0mg/ml	> 240	> 240	> 240
Ifosfamide	50.0mg/ml	-	> 240	> 240
Methotrexate	25.0mg/ml	> 240	> 240	-
Mitoxantrone	2.0mg/ml	-	> 240	> 240
Mitomycin C	0.5mg/ml	> 240	> 240	-
Paclitaxel (Taxol)	6.0mg/ml	> 240	> 240	> 240
*Thiotepa	10.0mg/ml	110.5	11.6	59.0
Vincristine Sulfate	1.0mg/ml	> 240	> 240	> 240
Warning Statement		Under the test conditions prescribed by the test, the minimum normalized breakthrough detection times for each of the 11 chemotherapy drugs tested exceeded the maximum testing time of 240 minutes except for Carmustine (BCNU) (3.3 mg/ml), which showed permeation time of 60.1 minutes, and Thiotepa (10 mg/ml), which showed permeation time of 110.5 minutes.	Please note that the following drugs have extremely low permeation time of less than 30 minutes: Carmustine (3.3 mg/ml) has a minimum breakthrough time of 10.1 minutes; Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 11.6 minutes.	CAUTION: Testing showed an average breakthrough time of 30.4 minutes for Carmustine and an average breakthrough time of 59.0 minutes for Thiotepa.

510(k) SUMMARY K161823

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		
		Predicate 1	**Predicate 2**	**Current**
510(k) Number		K153316	K152428	K161823
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010(E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500	Non-Irritating, under the conditions of the study	Under the conditions of the study (per ISO 10993-10), the device is not an irritant	Passes Not a primary skin irritant under the conditions of the study.
Biocompatibility	Dermal Sensitization - ISO 10993-10:2010(E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500.3(c)(4)	Non-sensitizing, under the conditions of the study	Under the conditions of the study (per ISO 10993-10), the device is not a sensitizer	Passes Not a contact sensitizer under the conditions of the study.
Size	Medical Glove Guidance Manual - Labeling	-	5½ 6.0 6½ 7.0 7½ 8.0 8½ 9.0	5½ 6.0 6½ 7.0 7½ 8.0 8½ 9.0
Single Use	Medical Glove Guidance Manual - Labeling	Single use	Single use	Single use
Sterility Status	Medical Glove Guidance Manual - Labeling	Sterile	Sterile	Sterile

7.0 Substantial Equivalence Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above (ASTM Requirements).

The device and the predicates share the same intended use, same material, same specifications for thickness and length, similar labeling according to the glove guidance, and same compliance with standards for physical properties, powder free, biocompatibility and water tightness. Thus, the device is substantially equivalent to the predicates.

Current device compliant to chemotherapy claim whereby glove thickness and length meets minimal thickness of 0.10 mm and minimal length of 270 respectively.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

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

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.