510(k) SUMMARY

K083305

JUN 18 2009

1.0 Submitter:

Name: Mr. Kirk Penner
Address: WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi,
43900 Sepang, Selangor Darul Ehsan, MALAYSIA
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Date of Summary Prepared: Nov 2008

2.0 Name of the device:

Powder Free Blue Nitrile Examination Gloves, Sterile with Chemotherapy Claim

Common Name: Exam Gloves

Classification Name: Patient Examination Gloves, Specialty Chemotherapy (21 CFR 880.6250 product code LZC)

510(K) Number: K083305

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

Powder-Free Blue Nitrile Examination Glove, Sterile

Company: WRP ASIA PACIFIC SDN BHD
510(k): K993313

4.0 Description of The Device:

Powder Free Blue Nitrile Examination Gloves, Sterile with Chemotherapy Claim meet all the requirements of ASTM standard D6978-05, D5712-05^{e1} and FDA 21 CFR 880.6250.

5.0 Intended Use of the Device:

The powder free chemotherapy examination glove is a specialty medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or forefinger to prevent contamination between examiner and patient bodily fluids, waste or environment. Tested for use with chemotherapy drugs. Tested chemotherapy drugs are as follows [Cyclophosphamide, Dacarbazine, Doxorubicin Hydrochloride; 5-Fluorouracil, Cisplatin, Etoposide, Vincristine Sulfate and Paclitaxel]

WARNING: DO NOT USE GLOVES WITH CARMUSTINE OR THIO-TEPA

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6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Blue Nitrile Examination Gloves, Sterile with Chemotherapy Claim are summarized with the following technological characteristics compared to ASTM D3578-01^{E1} or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE (Both Predicate and Current)
Dimensions	ASTM D6319-00a (2005) e-1	Meets
Physical Properties	ASTM D6319-00a (2005) e-1	Meets
Thickness	ASTM D6319-00a (2005) e-1	Meets
Powder Free	ASTM D6124-01	Meets ≤ 2 mg/glove
Biocompatability	Primary Skin Irritation	Passes (Not a primary skin irritant)
	Dermal Sensitization ASTM F-720-81	Passes (Not a contact sensitizer)
Watertight (1000ml)	ASTM D5151-06	Passes
*Resistance to permeation by Chemotherapy Drugs	ASTM D6978-05	Meets requirement
Sterile	Gamma Irradiated	Sterile (Dose Validation Report Attached)

Details and discussions of tests can be found in performance section

*Test Chemical and Concentration	Average breakthrough Detection Time (minutes)
*Dacarbazine 10mg/ml	>240
Cyclophosphamide (Cytoxan) 20mg/ml	>240
Doxorubicin Hydrochloride 2mg/ml	>240
*5-Flourouracil 50mg/ml	>240
Cisplatin 1mg/ml	>240
Etopside (Toposar) 20mg/ml	>240
Paclitaxel (Taxol) 6mg/ml	>240
Vincristine Sulfate 1mg/ml	>240

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Sterility:

- Product is labeled as sterile.
- Sterilization is achieved through gamma irradiation.
- SAL: 10^{-6}
- Method Used to validate sterilization cycle: Method 1 (ANSI/AAMI/ISO 11137) Sterilization of healthcare products – Radiation sterilization
- Radiation dose: Minimum 25kGy, Maximum 45kGy

Sterilizer:
Sterilgamma (M) Sdn Bhd
Lot 42, Rawang Integrated Industrial Park
48000 Rawang, Selangor
Malaysia

7.0 Substantial Equivalent 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.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

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

9.0 Conclusion

Powder Free Blue Nitrile Examination Gloves, Sterile with Chemotherapy Claim will perform according to the gloves performance standards referenced in section 6.0 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, the device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Mr. Kirk Penner
Head of Department,Regulatory Affairs
WRP Asia Pacific Sdn. Bhd.
Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru
Salak Tinggi, Sepang Selangor
MALAYSIA 43900

Re: K083305
Trade/Device Name: Powder Free Blue Nitrile Examination Gloves, Sterile with Chemotherapy Claim
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC
Dated: June 12, 2009
Received: June 16, 2009

Dear Mr. Penner:

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

Appendix G

WRP Asia Pacific Sdn Bhd
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Lot 1, Jalan 3, Kawasan Perusahaan
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Website www.wrpworld.com

Indications for Use

510(k) Number (if known): K083305

Applicant Name: **WRP ASIA PACIFIC SDN BHD**

Device Name:

Powder Free Blue Nitrile Examination Gloves, Sterile with Chemotherapy Claim

Indications for Use:

The powder free chemotherapy examination glove is a specialty medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or forefinger to prevent contamination between examiner and patient bodily fluids, waste or environment. Tested for use with chemotherapy drugs. Tested chemotherapy drugs are as follows [Cyclophosphamide, Dacarbazine, Doxorubicin Hydrochloride; 5-Fluorouracil, Cisplatin, Etoposide, Vincristine Sulfate and Paclitaxel]

WARNING: DO NOT USE GLOVES WITH CARMUSTINE OR THIO-TEPA

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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