K083409

JUL 29 2009

510(k) SUMMARY

1.0 Submitter:

Name: Mr. Kirk Penner
Address: WRP Asia Pacific Sdn Bhd
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Date of Summary Prepared: July 2008

2.0 Name of the device:

Powder Free Blue Latex Patient Examination Gloves, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim (≤50µg/dm^2 per glove of extractable protein)

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

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3.0 Identification of The Legally Marketed Devices:

Chemoplus Powder Free Blue latex Examination Gloves with Protein Labeling Claim 50 Micrograms or less.
Regulatory Class I
Product code: LYY
510(k): K972615

4.0 Description of The Device:

Powder Free Blue Latex Examination Gloves 18 Mil, with Chemotherapy Drugs & Protein Content Labeling Claim meets 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, Carmustine, Thio-Tepa, Dacarbazine, Doxorubicin Hydrochloride; 5- Fluorouracil, Cisplatin, Etoposide, and Paclitaxel]

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

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6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Blue Latex Patient Examination Gloves, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim (≤50µg/dm^2 per glove of extractable protein) are summarized with the following technological characteristics compared to ASTM D3578-05 or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE (Both Predicate and Current)
Dimensions	ASTM D3578-05	Meets
Physical Properties	ASTM D3578-05	Meets
Thickness	ASTM D3578-05	Meets
Powder Free	ASTM D6124-06	Meets ≤ 2 mg/glove
Protein Level	ASTM D5712-05^{e1}	Meets < 50 µg/g
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

CHARACTERISTICS	Predicate Device (K972615)	Current device
Resistance to permeation by Chemotherapy Drugs	Tested to ASTM F739-91 Meets requirement	ASTM D6978-05 Meets requirement

*Details and discussions of tests can be found in the performance section.

All other characteristics including appearance, thickness, material, psychical properties are equivalent to the predicate device. There is essentially no change to the device. This 510(k) submission is to seek approval for the device to be marketed with the ASTM D6978-05 claim on resistance to permeation by chemotherapy drugs.

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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 Latex Patient Examination Gloves, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim ($\leq$50µg/dm^2 per glove of extractable protein) 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

JUL 29 2009

Mr. Kirk Penner
Head of Department, Regulatory Affairs
WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3 Kawasan Perusahaan
Bandar Baru Salak Tinggi
49300 Sepang
Selangor Darul Ehsan
MALAYSIA

Re: K083409
Trade/Device Name: Powder Free Blue Latex Patient Examination Gloves, Tested for Use With Chemotherapy Drugs With a Protein Content Label Claim ($\leq 50 \mu g/dm^2$ Per Glove of Extractable Protein)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC, LZA
Dated: June 25, 2009
Received: July 1, 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 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/cdrh/mdr/ 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 (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 Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix B

WRP Asia Pacific Sdn Bhd
(147817-V)
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Indications for Use

510(k) Number (if known): K083409

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

Device Name:

Powder Free Blue Latex Patient Examination Gloves, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim (≤50µg/dm^2 per glove of extractable protein)

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, Carmustine, Thio-Tepa, Dacarbazine, Doxorubicin Hydrochloride; 5- Fluorouracil, Cisplatin, Etoposide, and Paclitaxel]

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

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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