NOV 2 2 2000

K003307

510(k) Summary

1.0 Submitter:

Name	:	WRP Specialty Products Sdn. Bhd.
Address	:	Lot 11, Jalan 2, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.	:	+60 3 8706 9788
Fax No.	:	+60 3 8706 5022

Date of Summary Prepared : June 16, 2000

2.0 Contact Person:

Name:	Mr. Mohd Haizan Hussein
Phone No.:	+60 3 8706 9788
Fax No.:	+60 3 8706 5022

3.0 Name of the device:

Trade Name	:	Dermagrip Powder Free Pink Polymer Coated Latex Examination Glove, Non-sterile (Protein Content Labeling)
Common Name	:	Examination Gloves
Classification Name:		Patient Examination Gloves (per 21 CFR 880.6250)

4.0 Identification of The Legally Marketed Device:

Class I patient examination gloves, 80LYY, powder free, that meets all the requirements of ASTM standard D 3578 - 00 and FDA 21 CFR 800.20.

5.0 Description of The Device:

The Powder Free Pink Polymer Coated Latex Examination Glove, Non-sterile (Protein Content Labeling) meets all the requirements of ASTM standard D 3578 - 00 and FDA 21 CFR 800.20.

6.0 Intended Use of the Device:

The Powder Free Pink Polymer Coated Latex Examination Glove, Non-sterile (Protein Content Labeling) are disposable devices intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

7.0 Summary of the Technological Characteristics of the Device:

The Powder Free Pink Polymer Coated Latex Examination Glove, Non-sterile (Protein Content Labeling) is summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standards	Device Performance
Dimensions	*ASTM D 3578 – 00*	*Meets*
Physical Properties	*ASTM D 3578 – 00*	*Meets*
Freedom from pinholes	*ASTM D 3578 – 00* *FDA 21 CFR 800.20*	*Meets*
Powder-Free	*ASTM D 6124 – 97*	*< 2 mg/glove*
Protein Level	*ASTM D 5712 – 95*	*< 50 µg/g*
Biocompatability	*Primary Skin Irritation in Rabbits*	*Passes* *(Not a primary skin irritant)*
	Dermal Sensitization	*Passes* *(Not a contact sensitizer)*

8.0 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.

9.0 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.

10.0 Conclusion

It can be concluded that the Dermagrip Powder Free Pink Polymer Coated Latex Examination Glove, Non-sterile (Protein Content Labeling) will perform according to the glove performance standards referenced in **Section 7** above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this 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

NOV 22 2000

Mr. Mohd Haizan Hussein
Manager of QA/RA
WRP Specialty Products SDN. BHD.
Lot 11, Jalan 2, Kawasan Perusahaan
Bandar Baru Salak Tinggi
43900 Sepang
Selangor Darul Ehsan
MALAYSIA

Re: K003307
Trade Name: Dermagrip Powder Free Pink Polymer Coated Latex Examination Gloves, Non-Sterile Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram
Regulatory Class: I
Product Code: LYY
Dated: October 23, 2000
Received: October 23, 2000

Dear Mr. Hussein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: WRP Specialty Products Sdn Bhd

510(k) Number (if known): K003307

Device Name: DERMAGRIP POWDER FREE PINK POLYMER COATED LATEX EXAMINATION GLOVE, NON-STERILE (PROTEIN CONTENT LABELING) Contains 50 m or less of total Water Extractable Protein per

Indications For Use:

The Powder Free Pink Polymer Coated Latex Examination Glove, Non-sterile (Protein Content Labeling) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter X

(Per 21 CFR 801.109)

Signed for Chun Lin

(Division Sign-Off)

Division of De

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