

4/23/99

WRP SPECIALTY PRODUCTS SDN BHD
(Company No: 112713-V)



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ATTACHMENT 3

KSP1044

CONTACT PERSON : C. H. KHOO

510(k) SUMMARY

1. Trade Name : DERMAGRIP POWDER FREE LATEX EXAMINATION GLOVE, NON STERILE (PROTEIN CONTENT LABELING) *50 micrograms or less per gram*
2. Common Name : Examination Gloves
3. Classification Name : Patient Examination Glove
4. Substantial Equivalence :

Class I natural rubber latex patient examination's glove, 80 LYY, powder free, protein content labeling. It meets all of the requirements of ASTM standard D3578-95.

5. Description of Device :

Class I natural rubber latex patient examination's glove, 80 LYY, powder free, protein content labeling. It meets all of the requirements of ASTM standard D3578-95.

6. Intended Use of Device :

The gloves are intended to be worn on the hand of healthcare personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.

7. **Summary of Performance Data :**

Performance data of gloves to ASTM D 3578-95 and FDA 1000 ml watertight test.

| TEST | ASTM D3578-95 | DERMAGRIP Powder Free Latex Examination Glove, Non Sterile (Protein Content Labeling) - refer to Attachment 9 of Device Test Report of Compliance |
|--|--|--|
| 1. Watertight (1000 ml) | S-4, AQL 4.0 | Pass based on 1) Single Sampling Plan, S-4, AQL 4.0, 2) Multiple Sampling Plan, GII, AQL 4.0 |
| 2. Length (mm) Size XS S M L XL | min 220 min 220 min 230 min 230 - | 245 255 297 249 253 |
| 3. Palm Width (mm) Size XS S M L XL | 70 ± 10 80 ± 10 95 ± 10 111 ± 10 - | 77 81 96 105 114 |
| 4. Single Wall Thickness (mm) Finger Palm | min 0.08 min 0.08 | 0.36 0.25 |

| TEST | ASTM D3578-95 | DERMAGRIP Powder Free Latex Examination Glove, Non Sterile (Protein Content Labeling) - refer to Attachment 9 of Device Test Report of Compliance |
|---|--|--|
| 5. Physical Properties <u>Before Aging :</u> Tensile Strength (MPa) Ultimate Elongation (%) <u>After Aging :</u> Tensile Strength (MPa) Ultimate Elongation (%) | min 14 min 700 min 14 min 500 | 28.63 962 18.43 1007 |
| 6. Powder Content | - | below 2 mg/glove |
| 7. Protein Content | - | below 50 microgram/gram |

8. **Substantial Equivalence based on Assessment of Non-Clinical Performance Data**

The performance test data of device as shown above indicate that this glove meets requirements of ASTM D 3578-95.

Protein content tested on recently manufactured and accelerated aging gloves using ASTM D5712 is below 50 microgram/gram.

9. **Conclusion**

This glove exceeds the ASTM D3578-95 requirements, meet FDA requirements for waterleak test on pinhole AQL and below 50 microgram/gram protein content labeling claim.

Date Summary Prepared : January 12, 1999.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 1999

Mr. Cheng Hean Khoo
Senior Manager, Regulatory/Environmental Management
WRP Specialty Products Sdn. Bhd.
Lot 11, Janal 2, Kawasan Perusahaan Bander
Baru Salak Tinggi,
43900 Sepang, Selangor Darul Ehsan,
MALAYSIA

Re: K991044
Trade Name: Dermagrip Powder-Free Latex Examination
Glove, Non-Sterile (Protein Content Labeling 50
micrograms or less)
Regulatory Class: I
Product Code: LYY
Dated: March 26, 1999
Received: March 30, 1999

Dear Mr. Cheng Hean Khoo:

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 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.

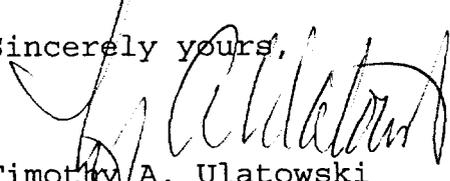
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Page 2 - Mr. Cheng Hean Khoo

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" (21 CFR 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/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

ATTACHMENT 2

Applicant : WRP Specialty Products Sdn. Bhd.

510(k) Number (if known) : K991044

Device Name : DERMAGRIP POWDER FREE LATEX EXAMINATION GLOVE, NON STERILE (PROTEIN CONTENT LABELING) (50 micrograms or Less)

Indications For Use :

1. The patient examination glove 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 _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use X

Chin S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991044