(4) DEC - 2 1999

K993214

WRP Specialty Products Sdn Bhd

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Bandar Baru Salak Tinggi,
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ATTACHMENT 3

CONTACT PERSON : S.K.OOI

510(k) SUMMARY

1. **Trade Name** : DERMAGRIP POWDER FREE LATEX SURGICAL GLOVE, STERILE (PROTEIN CONTENT LABELING) (20 micrograms max)
2. **Common Name** : Surgeon's Gloves
3. **Classification Name** : Surgeon's Glove
4. **Substantial Equivalence** :

   Class I natural rubber latex surgeon's glove, 79 KGO, powder free, protein content labeling. It meets all of the requirements of ASTM standard D3577-99.

5. **Description of Device** :

   Class I natural rubber latex surgeon's glove, 79 KGO, powder free, protein content labeling. It meets all of the requirements of ASTM standard D3577-99.

6. **Intended Use of Device** :

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

(5)

WRP Specialty Products Sdn Bhd

Attachment 3

7. **Summary of Performance Data** :

Performance data of gloves to ASTM D 3577-99 and FDA 1000 ml watertight test.

TEST	ASTM D 3577-99	DERMAGRIP Powder Free Latex Surgical Glove, Sterile (Protein Content Labeling) - refer to Attachment 7 of Device Test Report of Compliance
1.Watertight (1000 ml)	GI, AQL 1.5	Pass based on 1) Single Sampling Plan, GI, AQL 1.5, 2) Multiple Sampling Plan, GII, AQL 2.5
2. Length (mm) Size 5½ 6 6½ 7 7½ 8 8½ 9	 min 245 min 265 min 265 min 265 min 265 min 265 min 265 min 265	 294 300 298 309 291 308 304 301
3. Palm Width (mm) Size 5½ 6 6½ 7 7½ 8 8½ 9	 70 ± 6 76 ± 6 83 ± 6 89 ± 6 95 ± 6 102 ± 6 108 ± 6 114 ± 6	 72 77 83 90 98 102 108 114
4. Single Wall Thickness (mm) Finger Palm Cuff	 min 0.10 min 0.10 min 0.10	 0.27 0.24 0.20

TEST	ASTM D 3577-99	DERMAGRIP Powder Free Latex Surgical Glove, Sterile (Protein Content Labeling) - refer to Attachment 7 of Device Test Report of Compliance
5. Physical Properties		
Before Aging :		
Tensile Strength (MPa)	min 24	29.58
Ultimate Elongation (%)	min 750	902
Stress at 500% Elongation (MPa)	max 5.5	2.95
After Aging :		
Tensile Strength (MPa)	min 18	22.92
Ultimate Elongation (%)	min 560	902

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 3577-99.

9. **Conclusion**

This glove exceeds the ASTM D 3577-99 requirements, and also meet FDA requirements for water leak test on pinhole AQL.

Date Summary Prepared : August 10, 1999.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1999

Mr. Soo Kang Ooi
Manager, Regulatory Affairs/Quality Assurance
WRP Specialty Products Sdn. Bhd.
Lot 11, Jalan 2, Kawasan Perusahaan
Bandar Baru Salak Tinggi
43900 Sepang
Selangor Darul Ehsan, Malaysia

Re: K993214
Trade Name: Dermagrip Powder-Free Latex Surgical Glove, Sterile (Protein Content Labeling 50 micrograms or less)
Regulatory Class: I
Product Code: KGO
Dated: September 15, 1999
Received: September 24, 1999

Dear Mr. Ooi:

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.

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) : K993214

Device Name : DERMAGRIP POWDER FREE LATEX SURGICAL GLOVE, STERILE (PROTEIN CONTENT LABELING)
(50 micrograms or less)

Indications for Use :

1. The surgeon's glove is a device made of natural rubber intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993214