DEC - 2 1999

WRP Specialty Products Sdn Bhd

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Bandar Baru Salak Tinggi,
43900 Sepang,
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K993215

ATTACHMENT 3

CONTACT PERSON : S.K.OOI

510(k) SUMMARY

1. **Trade Name** : DERMAGRIP POWDERED LATEX SURGICAL GLOVE, STERILE

2. **Common Name** : Surgeon's Gloves

3. **Classification Name** : Surgeon's Glove

4. **Substantial Equivalence** :

   Class II natural rubber latex surgeon's glove, 79 KGO, powdered with absorbable dusting powder. It meets all of the requirements of ASTM standard D3577-99.

5. **Description of Device** :

   Class II natural rubber latex surgeon's glove, 79 KGO, powdered with absorbable dusting powder. It meets all of the requirements of ASTM standard D3577-99.

6. **Intended Use of Device** :

   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.

2. SUMMARIZED PROCEDURE OF THE QUALITY ASSURANCE METHODS FOR SURGICAL GLOVES

(2) K993215

2.1 REFERENCE

a) ASTM D 3577-99 - Standard Specification for Rubber SURGICAL Gloves.

b) ASTM D 412-87 - Standard Test Methods for Rubber Properties in Tension.

c) ISO 2859 - Sampling Procedures and Tables for Inspection by Attributes.

d) ANSI/ASQC Z1.4-1993 - Sampling Procedures and Tables for Inspection by Attributes.

2.2 SAMPLING

The gloves are sampled at random from a batch, where every part has an equal chance of being selected. The samples are selected and inspected in accordance with ISO 2859/ ANSI/ASQC Z1.4.

2.3 TEST METHODS

2.3.1 Physical Requirement Test

a) The tensile physical properties are determined as described in ASTM D412 using Type C dumb bell test pieces. Test pieces are evaluated to conform to physical requirement on before and after accelerated aging.

b) The accelerated aging is conducted by subjecting the test piece to a temperature of 100 °C ± 2 °C for 22 ± 0.3 hours.

c) **Quality Requirement**

	Before Aging	After Aging
Tensile Strength	Min 24 Mpa	Min 18 MPa
Ultimate Elongation	Min 750 %	Min 560 %
Stress at 500% Elongation	Max 5.5 Mpa	Not Applicable

d) The inspection level : ANSI/ASQC Z1.4, (S-2)

Batch Size : 300 000 pairs (based on one consignment quantity)
Sample Size : 13 pcs
AQL : 4.0
Accept : 1 pc
Reject : 2 pcs

(3)

Finished Powdered Gloves :

K993215

Average Powder Weights on Size 7 ½ Surgical Gloves

WRP Specialty Products Sdn. Bhd.	SIZE 7½ ACTUAL	POWDER WEIGHT*
	(%)	mg/glove
Internal : 0.5 –1.5%	1.41	204.7
External (Max) : 1.0%	0.96	140.0

Average over eight (8) pieces.

ATTACHMENTS

Number	Attached?	Subject
1.	(/) Yes ( ) No	Truthful & Accurate Statement
2.	(/) Yes ( ) No	Indications for Use Statement
3.	(/) Yes ( ) No	510(k) Summary
4.	(/) Yes ( ) No	Summary of Quality Assurance Testing Procedure of Dermagrip Powdered Latex Surgical Glove, Sterile
5.	(/) Yes ( ) No	Label, Labeling and Advertising
6.	(/) Yes ( ) No	Biocompability Test Reports
7.	(/) Yes ( ) No	Device Test Report of Compliance of Dermagrip Powdered Latex Surgical Glove, Sterile according to ASTM D3577-99 and FDA watertight test requirements.
8.	(/) Yes ( ) No	Validation on Gamma Radiation Sterilization Cycle.
9.	(/) Yes ( ) No	Packaging Use to Maintain the Sterility of the Gloves.
10.	(/) Yes ( ) No	Absorbable Dusting Powder Specification.
11.	(/) Yes ( ) No	Summary of Glove Physical Properties (refer to Attachment 7, Device Test Report of Compliance).
12.	( ) Yes (/) No	Non-USP Powder Information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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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: K993215
Trade Name: Powdered Latex Surgical Glove, Sterile
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) : K993215

Device Name : DERMAGRIP POWDERED LATEX SURGICAL GLOVE, STERILE

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)

Alice S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993215