

**WRP Specialty Products Sdn Bhd**

112713V

OCT 18 1999

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URL www.wrpworld.com**ATTACHMENT 3 (Revised)**

CONTACT PERSON : C. H. KHOO

K990752

510(k) SUMMARY

1. **Trade Name** : DERMAGRIP POWDER FREE NITRILE
EXAMINATION GLOVE, NON STERILE
2. **Common Name** : Examination Gloves
3. **Classification Name** : Patient Examination Glove
4. **Substantial Equivalence** :

Class I nitrile latex patient examination's glove, 80 LZA, powder free. It meets ASTM Standard D 3578-99 requirement for all properties with the exception of ultimate elongation.

5. **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.

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6. Summary of Performance Data :

Performance data of gloves to ASTM D 3578-99 standard and FDA 1000 ml watertight test.

TEST	ASTM D 3578-99	DERMAGRIP Powder Free Nitrile Examination Glove, Non Sterile - refer to Attachment 8 of Device Test Report of Compliance
1. Watertight (1000 ml)	G-1, AQL 2.5	Pass based on 1) Single Sampling Plan, G-I, AQL 2.5, 2) Multiple Sampling Plan, G-II, AQL 4.0
2. Length (mm)		
Size		
XS	min 220	-
S	min 220	260
M	min 230	245
L	min 230	248
XL	-	-
3. Palm Width (mm)		
Size		
XS	70 ± 10	-
S	80 ± 10	84
M	95 ± 10	95
L	111 ± 10	104
XL	-	-
4. Single Wall Thickness (mm)		
Finger	min 0.08	0.21
Palm	min 0.08	0.14



TEST	ASTM D 3578-99	DERMAGRIP Powder Free Nitrile Examination Glove, Non Sterile - refer to Attachment 6 of Device Test Report of Compliance
5. Physical Properties		
<u>Before Aging :</u>		
Tensile Strength (MPa)	min 14.0	29.50
Ultimate Elongation (%)	min 700	670
<u>After Aging :</u>		
Tensile Strength (MPa)	min 14.0	27.45
Ultimate Elongation (%)	min 500	583
6. Residual Powder	Less than 4mg/glove	Less than 2mg/glove

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

The performance test data of device as shown above indicate that these nitrile gloves meet ASTM D 3578-99 Standard Specification for Rubber Examination Gloves with the exception of ultimate elongation.

8. **Conclusion**

Based on the test results, these nitrile gloves meet the requirement of FDA's 1000ml Watertight Test and ASTM D 3578-99 requirement for tensile strength. Our in-house specifications for tensile strength is minimum 15.5 MPa and test results exceed the in-house specifications and ASTM D 3578-99 requirement for tensile strength.

Date Summary Prepared : March 25, 1999

(First amendment on May 24, 1999)

(Second amendment on July 20, 1999)

(Third amendment on October 7, 1999)

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Gloves For All Reasons™

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 18 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Cheng Hean Khoo
Sr. Manager, Regulatory/Environmental Management
WRP Specialty Products Sdn Bhd
Lot 11, Jalan 2, Kawasan Perusahaan
Bandar Baru Salak Tinggi
43900 Sepang
Selangor Darul Ehsan,
Malaysia

Re: K990752
Trade Name: Dermagrip Powder Free Blue Nitrile
Examination Glove, Non Sterile
Regulatory Class: I
Product Code: LZA
Dated: July 20, 1999
Received: July 28, 1999

Dear Mr. 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 (Pre-market 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

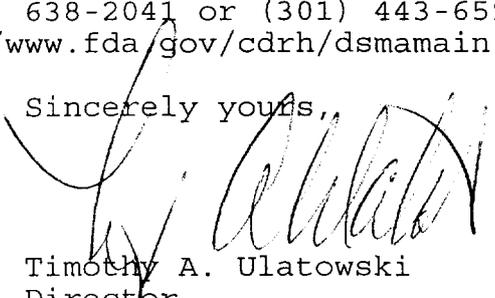
Page 2 - Mr. Khoo

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) : K990752

Device Name : DERMAGRIP POWDER FREE NITRILE EXAMINATION GLOVE, NON STERILE (Blue)

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

Chin S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K990752