



**WRP Asia Pacific Sdn Bhd**

FORMERLY KNOWN AS WEMBLEY RUBBER PRODUCTS (M) SDN BHD

147817V

K993311

NOV 19 1999

Lot 1, Jalan 3, Kawasan Perusahaan  
Bandar Baru Salak Tinggi,  
43900 Sepang,  
Selangor Darul Ehsan,  
**MALAYSIA**

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ATTACHMENT 3 (Revised)

CONTACT PERSON : Y. W. CHOW

510(k) SUMMARY

1. Trade Name : COMFIT POWDER FREE NITRILE EXAMINATION GLOVE, 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 for all properties with the exception of ultimate elongation before the aging test.

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	COMFIT Powder Free Nitrile Examination Glove, Sterile - refer to Attachment 8 of Device Test Report of Compliance
1. Watertight (1000 ml)	G-I, 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 S M L XL	min 220 min 220 min 230 min 230 -	- 248 250 260 -
3. Palm Width (mm)  Size       XS S M L XL	70 ± 10 80 ± 10 95 ± 10 111 ± 10 -	- 84 95 104 -
4. Single Wall Thickness  (mm) Finger  Palm	min 0.08  min 0.08	0.21  0.14



TEST	ASTM D 3578-99	COMFIT Powder Free Nitrile Examination Glove, Sterile - refer to Attachment 8 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 14.0  min 700  min 14.0  min 500	23.88  669  20.48  668
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 requirements of ASTM D 3578-99 Standard Specification for Rubber Examination Gloves with the exception of ultimate elongation before the aging test.

**8. Conclusion**

Based on the test results, these nitrile gloves meet the requirement of FDA's 1000 ml Watertight Test and ASTM D 3578-99 Standard Specification 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 : September 22, 1999  
(Amended on October 27, 1999)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 19 1999

Mr. Yue Wah Chow  
Head of RA/QA  
WRP Asia Pacific Sdn. Bhd.  
Lot 1, Jalan 3, Kawasan Perusahaan  
Bandar Baru Salak Tinggi  
43900 Sepang  
Selangor Darul Ehsan, Malaysia

Re: K993311  
Trade Name: Powder-Free Nitrile Examination Glove,  
Sterile  
Regulatory Class: I  
Product Code: LZA  
Dated: September 29, 1999  
Received: October 4, 1999

Dear Mr. Chow:

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.

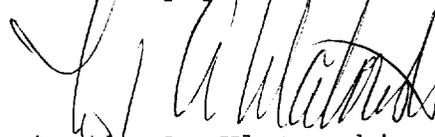
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

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 Asia Pacific Sdn. Bhd.

510(k) Number (if known) : K 993311

Device Name : COMFIT POWDER FREE NITRILE EXAMINATION GLOVE, STERILE

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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over-The-Counter Use X

Chen S. Liu

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

510(k) Number K 993311