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CONTACT PERSON: MR. Y. W. CHOW

Wembley Rubber Products (M) Sdn Bhd

Marketing / Factory

Lot 1, Jalan 3

Kawasan Perusahaan Bandar Baru

Salak Tinggi, 43900 SEPANG

Selangor, Malaysia

Telex: MA 39599 WRP

Tel: +603-846 1486

Fax: +603-846 1557

K953213

APPENDIX 4

510 (K) SUMMARY

1. **Trade Name** : COMFIT POWDER FREE LATEX EXAMINATION GLOVES (HYPOALLERGENIC, BEADED, PROTEIN LABELING CONTENT)
2. **Common Name** : Examination Gloves
3. **Classification Name** : Patient Examination Glove

4. **Substantial Equivalence** :

Class I latex patient examination glove 80 LYY, powder free, hypoallergenic, protein labeling content, that meets all of the requirements of ASTM standard D3578-91.

5. **Description of device** :

Class I latex patient examination glove 80 LYY, powder free, hypoallergenic, protein labeling content, that meets all of the requirements of ASTM standard D3578-91.

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.



7. Summary of Performance data :

Performance data of gloves to ASTM D 3578-91 and FDA 1000 ml watertight test.

TEST	ASTM D 3578-91	COMFIT Powder Free Latex Examination Gloves (Hypo, Beaded, Protein Labeling Content)
1. Watertight (1000 ml)	S-4, AQL 4.0	Pass based on AQL of 2.5
2. Length (mm)		
Size XS	-	240
S	min 230	242
M	min 230	238
L	min 230	239
XL	-	240
3. Palm width (mm)		
Size XS	-	79
S	80 ± 10	85
M	95 ± 10	96
L	111 ± 10	105
XL	-	110
4. Thickness (mm)		
Finger	min 0.08	0.25
Palm	min 0.08	0.19
5. Physical Properties		
<u>Before Ageing :</u>		
Tensile Strength (MPa)	min 21	28.4
Ultimate Elongation (%)	min 700	873
<u>After Ageing :</u>		
Tensile Strength (MPa)	min 16	25.8
Ultimate Elongation (%)	min 500	854
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 3578-91.

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

9. **Assessment of Clinical Performance data**

Clinical data of 200 Human subjects on Modified Draize test done on this glove demonstrated no potential for eliciting either dermal irritation or sensitization and support the labeling claim for "hypoallergenic".

10. **Conclusion**

This glove exceed the ASTM D 3578-91 requirements, meet pinhole FDA requirements, meet Hypoallergenic labeling claim and below 50 microgram / gram protein content labeling claim.

Date Summary Prepared : June 05, 1996