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510 (K) SUMMARY

1. Trade Name : COMFIT BROWN, BEADED SURGEON'S GLOVES (POWDERED, HYPOALLERGENIC)

2. Common Name : Surgeon Gloves

3. Classification Name : Surgeon Glove

4. Substantial Equivalence :

Class I natural rubber latex surgeon glove, 79 KGO, powdered with absorbable dusting powder, hypoallergenic, that meets all of the requirements of ASTM standard D3577-91.

5. Description of device :

Class I natural rubber latex surgeon glove, 79 KGO, powdered with absorbable dusting powder, hypoallergenic, that meets all of the requirements of ASTM standard D3577-91.

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 3577-91 and FDA 1000 ml watertight test.

TEST	ASTM D 3577-91	COMFIT Brown Beaded Surgeon's Gloves (Powdered,Hypo)
1. Watertight (1000 ml)	S-4,AQL 1.5	Pass based on AQL of 1.0
2. Length (mm)		
Size		
5.5	min 245	260
6.0	min 265	265
6.5	min 265	265
7.0	min 265	270
7.5	min 265	302
8.0	min 265	302
8.5	min 265	302
9.0	min 265	302
3. Palm width (mm)		
Size		
5.5	70 ± 6	72
6.0	76 ± 6	77
6.5	83 ± 6	83
7.0	89 ± 6	89
7.5	95 ± 6	96
8.0	102 ± 6	102
8.5	108 ± 6	108
9.0	114 ± 6	114
4. Thickness (mm)		
Finger	min 0.10	0.25
Palm	min 0.10	0.21
5. Physical Properties		
<u>Before Ageing :</u>		
Tensile Strength (MPa)	min 24	26.0
Ultimate Elongation (%)	min 750	855
<u>After Ageing :</u>		
Tensile Strength (MPa)	min 18	23.4
Ultimate Elongation (%)	min 560	890

6. **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 3577-91

7. **Assessment of Clinical Performance data**

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

8. **Conclusion**

This glove exceed the ASTM D 3577-91 requirements, meet pinhole FDA requirements , meet Hypoallergenic labeling claim.

Date Summary Prepared : January 06, 1996