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510 (K) SUMMARY

1. **Trade Name** : COMFIT MICROPTIC, 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.

COMFIT MICROPTIC brown surgical gloves are 0.15 mm (minimum) thick single wall to increase finger sensitivity during micro-surgery.

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.

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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	COMPTON OPTIC Brown Dusted Surgical Gloves (Standard Size)
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	298
8.0	min 265	298
8.5	min 265	298
9.0	min 265	298
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	95
8.0	102 ± 6	102
8.5	108 ± 6	108
9.0	114 ± 6	114
4. Thickness (mm)		
Finger	min 0.10	0.20
Palm	min 0.10	0.17
5. Physical Properties		
<u>Before Ageing :</u>		
Tensile Strength (MPa)	min 24	24.97
Ultimate Elongation (%)	min 750	862
<u>After Ageing :</u>		
Tensile Strength (MPa)	min 18	19.66
Ultimate Elongation (%)	min 560	863

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 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".

8. Conclusion

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

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