

**K953213 COMFIT (POWDER FREE EXAMINATION GLOVES
(HYPOALLERGENIC, LOW PROTEIN, BEADED))**Oct 11, 1996
459 days to decisionK953213 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k953213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 10, 1995
Decision date	Oct 11, 1996
Days to decision	459 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wembley Rubber Products (M) Sdn Bhd
Location	Kuala Lumpur, Malaysia, MY
Contact	ONG G CHEE
510(k) history	61 submissions · 61 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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