

K953590 COMFITJun 27, 1996
332 days to decisionK953590 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k953590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 31, 1995
Decision date	Jun 27, 1996
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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