

**K936266 COMFIT PINK POWDERED EXAMINATION GLOVES
(HYPOALLERGENIC)**

Apr 13, 1995
469 days to decision

K936266 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k936266/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 30, 1993
Decision date	Apr 13, 1995
Days to decision	469 days
Third-party review	No
Summary / Statement	Statement

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k936266/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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