

K951468 COMFITApr 28, 1995
29 days to decisionK951468 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k951468/>**SUBMISSION DETAILS**

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|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 30, 1995 |
| Decision date | Apr 28, 1995 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Statement |

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/k951468/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026