

K943601 COMFIT (PINK)May 17, 1995
296 days to decisionK943601 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k943601/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Jul 25, 1994 |
| Decision date | May 17, 1995 |
| Days to decision | 296 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.netDevice record: <https://www.510kdatabase.net/k943601/> 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