

**K942947 COMFIT EXAMINATION GLOVES, POWDER FREE,
HYPOALLERGENIC**Nov 30, 1994
160 days to decisionK942947 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k942947/>**SUBMISSION DETAILS**

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|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Jun 23, 1994 |
| Decision date | Nov 30, 1994 |
| Days to decision | 160 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/k942947/>; 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