

**K962189 COMFIT POWDER FREE GREEN EXAMINATION
GLOVES (HYPOALLERGENIC, LOW PROTEIN)**Jul 26, 1996
50 days to decisionK962189 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k962189/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Jun 6, 1996 |
| Decision date | Jul 26, 1996 |
| Days to decision | 50 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Wembley Rubber Products (M) Sdn Bhd |
| Location | Kuala Lumpur, Malaysia, MY |
| Contact | CHOW YUE WAH |
| 510(k) history | 61 submissions · 61 cleared · 1990-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962189/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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