

**K993664 SYNTHETIC VINYL MEDICAL EXAMINATION
POWDERED GLOVES**

Jan 11, 2000
74 days to decision

K993664 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k993664/>

SUBMISSION DETAILS

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Vinyl Patient Examination Glove (LYZ) |
| Date received | Oct 29, 1999 |
| Decision date | Jan 11, 2000 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Top Glove Sdn. Bhd. |
| Location | Malaysia, ML |
| Contact | WEE-CHAI LIM |
| 510(k) history | 17 submissions · 17 cleared · 1991-2020 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k993664/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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