

**K010719 POWDER-FREE NITRILE PATIENT EXAMINATION
GLOVE, PURPLE COLOR**Apr 10, 2001
29 days to decisionK010719 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k010719/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Mar 12, 2001 |
| Decision date | Apr 10, 2001 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Perusahaan Getah Asas Sdn. Bhd. |
| Location | 42000 Port Kelang, S.D.E., MY |
| Contact | KONG C TAN |
| 510(k) history | 30 submissions · 30 cleared · 1989-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010719/>; 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 July 2, 2026