

K982691 MULTI-COMFORT POWDERED EXAMINATION GLOVES WITH PROTEIN CONTENT LABELING CLAIM (200 MICROGRAMS OR LESS)Oct 9, 1998
67 days to decisionK982691 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k982691/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Aug 3, 1998 |
| Decision date | Oct 9, 1998 |
| Days to decision | 67 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Perusahaan Intan Emas Sdn. Bhd. |
| Location | Beranang, Selangor, D.E., MY |
| Contact | BIEN LONG NIEN |
| 510(k) history | 4 submissions · 4 cleared · 1989-1998 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982691/> 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 5, 2026