

**K013317 TEKMEDIC POWDER-FREE WITH PROTEIN LABELING
CLAIM (50 MICROGRAMS OR LESS)**Dec 17, 2001
74 days to decisionK013317 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k013317/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Oct 4, 2001 |
| Decision date | Dec 17, 2001 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Tekmedic (M) Sdn Bhd |
| Location | Kuala Lumpur, MY |
| Contact | KOK-KEE HON |
| 510(k) history | 11 submissions · 11 cleared · 1989-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013317/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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