

**K123469 POWDER FREE NITRILE PATIENT EXAMINATION
GLOVE, BLUE AND WHITE COLORED, NON-STERILE**Feb 19, 2013
98 days to decisionK123469 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k123469/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Nov 13, 2012 |
| Decision date | Feb 19, 2013 |
| Days to decision | 98 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Wear Safe (Malaysia) Sdn Bhd - Facility II |
| Location | Mukim Kapar, Klang, Selangor, MY |
| Contact | ALEX YOONG |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123469/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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