

K083156 NON STERILE POWDER FREE NITRILE EXAMINATION GLOVES, BLUE

May 8, 2009
196 days to decision

K083156 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k083156/>

SUBMISSION DETAILS

| | |
|-----------------------|-----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Oct 24, 2008 |
| Decision date | May 8, 2009 |
| Days to decision | 196 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Giga-Drive Sdn, Bhd |
| Location | Ipoh, Perak, MY |
| Contact | IAN NG TZE CHEU |
| 510(k) history | 1 submissions · 1 cleared · 2009-2009 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083156/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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