

**K133949 POWDER FREE NITRILE PATIENT EXAMINATION
GLOVE,BLUE AND ORANGE COLORED,NON-STERILE TESTED
FOR USE WITH CHEMOTHERAPY DRUGS**

Apr 8, 2014
106 days to decision

K133949 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k133949/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 23, 2013
Decision date	Apr 8, 2014
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Top Calibre Sdn Bhd
Location	Shah Alam, MY
Contact	ROSNITA MAODIN
510(k) history	5 submissions · 5 cleared · 2012-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k133949/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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