

**K112612 POWDER FREE LATEX PATIENT EXAMINATION
GLOVE, WITH PROTEIN CONTENT LABELING CLAIM**Jan 18, 2012
133 days to decisionK112612 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k112612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 7, 2011
Decision date	Jan 18, 2012
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112612/> 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 June 7, 2026