

**K091965 POWDER FREE NITRILE EXAMINATION GLOVES
BLACK**Nov 24, 2009
146 days to decisionK091965 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k091965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 1, 2009
Decision date	Nov 24, 2009
Days to decision	146 days
Third-party review	No
Summary / Statement	Statement
Other names	BLUE, GRAPE SCENTED

APPLICANT

Company	Platinum Glove Industries Sdn. Bhd.
Location	Kuala Lumpur, MY
Contact	SO SOON CHEAW
510(k) history	6 submissions · 6 cleared · 2005-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091965/> 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 22, 2026