

K142270 LATEX POWDERED EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM OF 200 MICROGRAM OR LESS PER GRAM OF GLOVENov 25, 2014
102 days to decisionK142270 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k142270/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 15, 2014
Decision date	Nov 25, 2014
Days to decision	102 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdb. Bhd.
Location	Bandar Sri Damansara, MY
Contact	KUAN KAM HON
510(k) history	4 submissions · 4 cleared · 2014-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142270/> 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 2, 2026