

K160560 Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (Blue)Aug 4, 2016
157 days to decisionK160560 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k160560/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 29, 2016
Decision date	Aug 4, 2016
Days to decision	157 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	KUAN KAM HON
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160560/> 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 18, 2026