

K162646 Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim (Blue)Mar 3, 2017
162 days to decisionK162646 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k162646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 22, 2016
Decision date	Mar 3, 2017
Days to decision	162 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega NGC Sdn. Bhd.
Location	Bandar Sri Damansara, MY
Contact	KUAN MUN LEONG
510(k) history	28 submissions · 28 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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