

K132006 STERILE NITRILE POWDER FREE EXAMINATION GLOVE(VBLU), STERILE NITRILE POWDER FREE EXAMINATION GLOVE(ABLU)

Nov 7, 2013
129 days to decision

K132006 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k132006/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 1, 2013
Decision date	Nov 7, 2013
Days to decision	129 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	NURUL AISYAH KONG
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132006/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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