

**K120336 NITRILE POWDER FREE EXAMINATION GLOVES (VIO)
TESTED FOR USE WITH CHENITRILE POWDER FREE
EXAMINATION (ABLU) TESTED FOR U**Jun 25, 2012
143 days to decisionK120336 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k120336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Feb 3, 2012
Decision date	Jun 25, 2012
Days to decision	143 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.netDevice record: <https://www.510kdatabase.net/k120336/> 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