

**K091652 NITRILE POWDER FRE EXAMINATION GLOVES
(BLUE) TESTED FOR USE WITH CHEMOTHERAPY DRUGS**

Sep 4, 2009
87 days to decision

K091652 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k091652/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 9, 2009
Decision date	Sep 4, 2009
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k091652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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