

K061074 ABLE GLOVE, NITRILE BLUE POWDERED EXAMINATION GLOVES

May 24, 2006
37 days to decision

K061074 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k061074/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 17, 2006
Decision date	May 24, 2006
Days to decision	37 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bright Element Sdn Bhd
Location	Klang Selangor Darul Ehsan, MY
Contact	SEOW L AUDIE
510(k) history	4 submissions · 4 cleared · 2006-2007

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k061074/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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