

**K063777 ABLE GLOVE NITRILE BLUE POWDER FREE
EXAMINATION GLOVE**Feb 23, 2007
63 days to decisionK063777 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k063777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 22, 2006
Decision date	Feb 23, 2007
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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