

**K063776 ABLE GLOVE LATEX POWDERED EXAMINATION
GLOVES**Mar 2, 2007
71 days to decisionK063776 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k063776/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 21, 2006
Decision date	Mar 2, 2007
Days to decision	71 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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