

K120693 LATEX EXAMINATION GLOVES (POWDERED)May 8, 2012
62 days to decisionK120693 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k120693/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 7, 2012
Decision date	May 8, 2012
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Top Calibre Sdn Bhd
Location	Shah Alam, MY
Contact	TRACY NGUI
510(k) history	5 submissions · 5 cleared · 2012-2014

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