

K123819 MULTIPLE NAMEMar 5, 2013
83 days to decisionK123819 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k123819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 12, 2012
Decision date	Mar 5, 2013
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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