

**K994354 POLYMER COATED, POWDER FREE, LATEX
EXAMINATION GLOVES WITH PROTEIN CONTENT LABELING
CLAIM (50 MICROGRAMS OR LESS)**Jan 31, 2000
39 days to decisionK994354 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k994354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 23, 1999
Decision date	Jan 31, 2000
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Flexitech Sdn. Bhd.
Location	Klang, Selangor, MY
Contact	Y. F HEW
510(k) history	6 submissions · 6 cleared · 1999-2000

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