

**K993529 POWDER FREE LATEX EXAMINATION GLOVES,
POLYMER COATED WITH PROTEIN CONTENT LABELING
CLAIM (50 MICROGRAMS OR LESS)**Dec 29, 1999
72 days to decisionK993529 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k993529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 18, 1999
Decision date	Dec 29, 1999
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biografik (Malaysia) Sdn Bhd
Location	Nilai, Negeri Sembilan, MY
Contact	SHUKUR BIN HASRAN
510(k) history	2 submissions · 2 cleared · 1996-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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