

**K971403 SMART - GLOVE POWDER FREE LATEX
EXAMINATION GLOVE**May 29, 1997
44 days to decisionK971403 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k971403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 15, 1997
Decision date	May 29, 1997
Days to decision	44 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sj Medical Products (M) Sdn Bhd
Location	Klang, Selangor, MY
Contact	FOO KNON PU
510(k) history	5 submissions · 5 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971403/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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