

**K973801 HIGH RISK POWDERFREE LATEX EXAMINATION
GLOVES (BLUE COLOUR)**Nov 21, 1997
46 days to decisionK973801 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k973801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 6, 1997
Decision date	Nov 21, 1997
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sri Johani Sdn. Bhd.
Location	Malaysia, MY
Contact	LIM L AIK
510(k) history	23 submissions · 23 cleared · 1989-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973801/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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