

K973904 POLYMER LATEX EXAMINATION GLOVES

Dec 17, 1997
64 days to decision

K973904 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k973904/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 14, 1997
Decision date	Dec 17, 1997
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k973904/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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