FDA 510(k) Premarket Notification

K973815 HIGH RISK POWDERED LATEX EXAMINATION GLOVES (BLUE COLOUR)

CLEARED

Nov 21, 1997
45 days to decision

K973815 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k973815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 7, 1997
Decision date	Nov 21, 1997
Days to decision	45 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