

**K973815 HIGH RISK POWDERED LATEX EXAMINATION GLOVES (BLUE COLOUR)**

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k973815/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026