

K961634 NIL - POWDER-FREE LATEX EXAMINATION GLOVESJun 16, 1997
413 days to decisionK961634 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k961634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 29, 1996
Decision date	Jun 16, 1997
Days to decision	413 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	HI Rubber Products Sdn Bhd
Location	Alexandria, VA, US
Contact	YUNUS LATIF
510(k) history	2 submissions · 2 cleared · 1997-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961634/> 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 2, 2026