

**K974443 POWDER FREE NITRILE EXAMINATION GLOVES -
POLYMER COATED**Jan 5, 1998
41 days to decisionK974443 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k974443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Nov 25, 1997
Decision date	Jan 5, 1998
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	P.T. Latexindo Tobaperkasa
Location	Medan, ID
Contact	HENDRA RAMALI
510(k) history	3 submissions · 3 cleared · 1997-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974443/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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