

K974185 POLYMER NITRILE EXAMINATION GLOVESDec 18, 1997
42 days to decisionK974185 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k974185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 6, 1997
Decision date	Dec 18, 1997
Days to decision	42 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974185/> 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