

**K992557 QUALATEX POWDERED LATEX EXAMINATION
GLOVES**Sep 14, 1999
46 days to decisionK992557 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k992557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 30, 1999
Decision date	Sep 14, 1999
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tan Sin Lian Industries Sdn. Bhd.
Location	Philadelphia, PA, US
Contact	TAN TIOW GIN
510(k) history	2 submissions · 2 cleared · 1999-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992557/>. 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