

K892101 PATIENT EXAM GLOVES (MFG. SHUN TAHI RUBBER GLOVES)May 8, 1989
35 days to decisionK892101 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k892101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 3, 1989
Decision date	May 8, 1989
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Ergo Intl., Ent., Inc.
Location	North Miami Beach, FL, US
Contact	BERTHA ERTEL
510(k) history	5 submissions · 5 cleared · 1988-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k892101/> 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 8, 2026