

K051913 POWDERED LATEX PATIENT EXAMINATION GLOVESSep 30, 2005
77 days to decisionK051913 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k051913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 15, 2005
Decision date	Sep 30, 2005
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shinemound Enterprise, Inc.
Location	North Billerica, MA, US
Contact	HUAN-CHUNG LI
510(k) history	8 submissions · 8 cleared · 1997-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k051913/> 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 1, 2026