

K954487 PRE POWDERED LATEX EXAMINATION GLOVESMar 15, 1996
170 days to decisionK954487 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k954487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 27, 1995
Decision date	Mar 15, 1996
Days to decision	170 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ganz Industries Sdn. Bhd.
Location	Nilai 71800, Negeri Sembilan, MY
Contact	GAN SEONG KHIAM
510(k) history	4 submissions · 4 cleared · 1995-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954487/> 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 6, 2026