

K913409 LATEX EXAMINATION GLOVESSep 27, 1991
59 days to decisionK913409 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k913409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 30, 1991
Decision date	Sep 27, 1991
Days to decision	59 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Top Glove Sdn. Bhd.
Location	Malaysia, ML
Contact	BEE TONG
510(k) history	17 submissions · 17 cleared · 1991-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913409/> 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 June 29, 2026