

K980194 POWDERFREE LATEX EXAMINATION GLOVESMar 13, 1998
52 days to decisionK980194 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k980194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 20, 1998
Decision date	Mar 13, 1998
Days to decision	52 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Besglove Medicare Sdn. Bhd.
Location	Kajang, Selangor Darul, Ehasan, MY
Contact	LEE AIK LIM
510(k) history	22 submissions · 22 cleared · 1997-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980194/> 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 4, 2026