

**K991745 ROYAL SHIELD NON-STERILE POWDER-FREE,
GREEN LATEX EXAMINATION GLOVES WITH A PROTEIN
CONTENT LABELING CLAIM (50 MICROGRAM**

Jun 23, 1999
33 days to decision

K991745 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k991745/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 21, 1999
Decision date	Jun 23, 1999
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shield Gloves Manufacturer (M) Sdn Bhd
Location	Petaling Jaya, MY
Contact	E. J. SMITH
510(k) history	18 submissions · 18 cleared · 1994-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k991745/>; 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