

**K100694 COLORED POWDER FREE AND POLYMER COATED
EXAMINATION GLOVE (BLUE, BLACK AND PINK) WITH A
PROTEIN CLAIM OF LESS THAN**Jun 25, 2010
106 days to decisionK100694 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k100694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 11, 2010
Decision date	Jun 25, 2010
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tekmedic (M) Sdn Bhd
Location	Kuala Lumpur, MY
Contact	PATRICK LEONG
510(k) history	11 submissions · 11 cleared · 1989-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100694/>; 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 9, 2026