

K000555 TEKMEDIC POWDERED SINGLE-USE LATEX PATIENT EXAMINATION GLOVES WITH PROTEIN & POWDER LABEL CLAIM CONTAINS 70MGM OR LESS O

Apr 12, 2000
54 days to decision

K000555 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k000555/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Feb 18, 2000
Decision date	Apr 12, 2000
Days to decision	54 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k000555/> 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