

**K994416 POLYMER COATED POWDER FREE NITRILE
EXAMINATION GLOVES, BLUE**Feb 3, 2000
36 days to decisionK994416 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k994416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 29, 1999
Decision date	Feb 3, 2000
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Flexitech Sdn. Bhd.
Location	Klang, Selangor, MY
Contact	Y. F HEW
510(k) history	6 submissions · 6 cleared · 1999-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994416/> 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