

**K001280 COMFIT POWDER FREE POLYMER COATED LATEX
EXAMINATION GLOVE, NON STERILE WITH PROTEIN
LABELING CLAIM (50 MICROGRAMS OR LES**May 15, 2000
24 days to decisionK001280 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k001280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 21, 2000
Decision date	May 15, 2000
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wrp Asia Pacific Sdn. Bhd.
Location	Salak Tinggi, Sepang Selangor, MY
Contact	YUE WAH CHOW
510(k) history	46 submissions · 46 cleared · 1999-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001280/> 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 28, 2026