

**K980605 LOW PROTEIN LATEX PATIENT EXAMINATION
GLOVES (POWDER-FREE)**Apr 14, 1998
56 days to decisionK980605 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k980605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Feb 17, 1998
Decision date	Apr 14, 1998
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Sarana Indoprotex
Location	Lampung 35001-Indonesia, IO
Contact	ELLEN HUTAPEA
510(k) history	4 submissions · 4 cleared · 1992-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980605/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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