

K913531 PATIENT EXAMINATION GLOVEWSJan 7, 1992
152 days to decisionK913531 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k913531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 8, 1991
Decision date	Jan 7, 1992
Days to decision	152 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Sarana Indoprotex
Location	Lampung 35001-Iodonesia, IO
Contact	TIONG GIE
510(k) history	4 submissions · 4 cleared · 1992-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913531/> 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 5, 2026