

**K980848 HYPOALLERGENIC LATEX PATIENT EXAM GLOVES-
PREPOWDERED**Apr 28, 1998
55 days to decisionK980848 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k980848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 4, 1998
Decision date	Apr 28, 1998
Days to decision	55 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	P.T. Irama Dinamika Latex
Location	Medan - Indonesia, ID
Contact	ANIL TANEJA
510(k) history	11 submissions · 11 cleared · 1991-1999

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