

K984449 NATURAL RUBBER PRE-POWDERED COLORED & FLAVORED PATIENT EXAMINATION GLOVES WITH PROTEIN LABELLING CLAIM

Mar 19, 1999
95 days to decision

K984449 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k984449/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 14, 1998
Decision date	Mar 19, 1999
Days to decision	95 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k984449/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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