FDA 510(k) Premarket Notification

K892089 PATIENT EXAMINATION GLOVES (LATEX)

CLEARED

Jul 14, 1989
102 days to decision

K892089 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k892089/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 3, 1989
Decision date	Jul 14, 1989
Days to decision	102 days
Third-party review	No

APPLICANT

Company	**N.V. Kalibaru**
Location	Bandung, ID
Contact	HADI SUGANDA
510(k) history	1 submissions · 1 cleared · 1989-1989

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k892089/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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