FDA 510(k) Premarket Notification

K891566 VINYL EXAM GLOVES (MFG. AM GLOVES CO. LTD.)

CLEARED

Apr 11, 1989
25 days to decision

K891566 · Product code: **LYZ** · General Hospital
Source: https://www.510kdatabase.net/k891566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Mar 17, 1989
Decision date	Apr 11, 1989
Days to decision	25 days
Third-party review	No

APPLICANT

Company	**Neo-Sigma, Inc.**
Location	Dallas, TX, US
Contact	ALEX LAI
510(k) history	4 submissions · 4 cleared · 1989-1989

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k891566/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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