FDA 510(k) Premarket Notification

K910631 SUNTEX STERILE EXAM GLOVES

CLEARED

Mar 7, 1991
22 days to decision

K910631 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k910631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Feb 13, 1991
Decision date	Mar 7, 1991
Days to decision	22 days
Third-party review	No

APPLICANT

Company	**P.T. Latexindo Prautama**
Location	Chester, NJ, US
Contact	ROBERT S KENNEDY
510(k) history	3 submissions · 3 cleared · 1989-1991

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k910631/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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