FDA 510(k) Premarket Notification

K915636 GLOVE CHECK PATIENT EXAMINATION GLOVE LEAK DETECT.

CLEARED

Jul 13, 1992
209 days to decision

K915636 · Product code: **LDQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k915636/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Dec 17, 1991
Decision date	Jul 13, 1992
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Associated Ent., Inc.**
Location	Danville, CA, US
Contact	EDDI LEACH
510(k) history	4 submissions · 4 cleared · 1989-1993

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k915636/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 6, 2026