

K900338 VISUWELL(R) REAGIN TEST (MODIFICATION)Apr 10, 1990
77 days to decisionK900338 · Product code: **GMQ** · Microbiology
Source: <https://www.510kdatabase.net/k900338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Jan 23, 1990
Decision date	Apr 10, 1990
Days to decision	77 days
Third-party review	No

APPLICANT

Company	Adi Diagnostics, Inc.
Location	Rexdale, Ontario, CA
Contact	SHAW
510(k) history	4 submissions · 4 cleared · 1989-1991

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