

K972182 ABBOTT STREP A CONTROLSAug 13, 1997
76 days to decisionK972182 · Product code: **MJZ** · Microbiology
Source: <https://www.510kdatabase.net/k972182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Direct Antigen, Positive Control (MJZ)
Date received	May 29, 1997
Decision date	Aug 13, 1997
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diagnostics
Location	Mountain View, CA, US
Contact	GRACE LEMIEUX
510(k) history	28 submissions · 28 cleared · 1981-1997

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