

**K935554 QUIKPAC II ONESTEP STREP A
IMMUNOCHROMATOGRAPHIC ASSAY**Aug 30, 1995
651 days to decisionK935554 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k935554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Nov 17, 1993
Decision date	Aug 30, 1995
Days to decision	651 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syntron Bioresearch, Inc.
Location	San Diego, CA, US
Contact	JAMES P LEE, PH.D.
510(k) history	26 submissions · 26 cleared · 1987-1999

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