

**K935475 QUIKSTRIP ONESTEP STREP A TEST
IMMUNOCHROMA ASSAU**Aug 30, 1995
653 days to decisionK935475 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k935475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Nov 15, 1993
Decision date	Aug 30, 1995
Days to decision	653 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935475/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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