

K961423 OSOM STREP A TESTOct 11, 1996
182 days to decisionK961423 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k961423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Apr 12, 1996
Decision date	Oct 11, 1996
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wyntek Diagnostics, Inc.
Location	San Diego, CA, US
Contact	SHU-CHING CHENG
510(k) history	12 submissions · 12 cleared · 1995-2000

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