

**K880665 MODIFIED GROUP A STREPTOCOCCUS DETECTION
KIT**Mar 1, 1988
12 days to decisionK880665 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k880665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Feb 18, 1988
Decision date	Mar 1, 1988
Days to decision	12 days
Third-party review	No

APPLICANT

Company	Allelix Diagnostics, Inc.
Location	Canada L4v 1p1, CA
Contact	JANET SHAW
510(k) history	2 submissions · 2 cleared · 1988-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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