

K852841 RAPID DIRECT STREP A LATEX AGGLUTINATION TESTJul 24, 1985
19 days to decisionK852841 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k852841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Jul 5, 1985
Decision date	Jul 24, 1985
Days to decision	19 days
Third-party review	No

APPLICANT

Company	Smithkline Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	RONALD J SCHOENGOLD
510(k) history	42 submissions · 42 cleared · 1976-1996

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