

K834582 DETECT GROUP A STREP TESTApr 4, 1984
97 days to decisionK834582 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k834582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Dec 29, 1983
Decision date	Apr 4, 1984
Days to decision	97 days
Third-party review	No

APPLICANT

Company	Difco Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	121 submissions · 121 cleared · 1979-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k834582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026