

K864206 REVEAL COLOUR STREP A ZL16Jan 13, 1987
78 days to decisionK864206 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k864206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Oct 27, 1986
Decision date	Jan 13, 1987
Days to decision	78 days
Third-party review	No

APPLICANT

Company	Wellcome Diagnostics
Location	Walker, MI, US
Contact	MOODY, PH.D.
510(k) history	28 submissions · 28 cleared · 1983-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864206/>; 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 June 29, 2026