

K951542 DIRECTIGEN 1-2-3 GROUP A STREP TESTOct 20, 1995
200 days to decisionK951542 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k951542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Apr 3, 1995
Decision date	Oct 20, 1995
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
Contact	JUDITH J SMITH
510(k) history	632 submissions · 625 cleared · 1976-2001

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