

K854978 DIFCO STREP A LATEX TESTMar 18, 1986
96 days to decisionK854978 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k854978/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, All Groups, Streptococcus Spp. (GTZ) |
| Date received | Dec 12, 1985 |
| Decision date | Mar 18, 1986 |
| Days to decision | 96 days |
| Third-party review | No |

APPLICANT

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

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