

K843590 DETECT-A-STREPOct 30, 1984
48 days to decisionK843590 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k843590/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, All Groups, Streptococcus Spp. (GTZ) |
| Date received | Sep 12, 1984 |
| Decision date | Oct 30, 1984 |
| Days to decision | 48 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Antibodies, Inc. |
| Location | Mchenry, IL, US |
| Contact | JAY BANOVTZ |
| 510(k) history | 16 submissions · 16 cleared · 1977-1989 |

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