

K911417 ICON STREP B IMMUNOENZYMETRIC ASSAYJul 24, 1991
114 days to decisionK911417 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k911417/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, All Groups, Streptococcus Spp. (GTZ) |
| Date received | Apr 1, 1991 |
| Decision date | Jul 24, 1991 |
| Days to decision | 114 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Hybritech, Inc. |
| Location | Mchenry, IL, US |
| Contact | JOANNE MARTINIS |
| 510(k) history | 63 submissions · 63 cleared · 1981-1997 |

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