

K902991 ICON STREP B IMMUNOENZYMETRIC ASSAYOct 3, 1990
86 days to decisionK902991 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k902991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jul 9, 1990
Decision date	Oct 3, 1990
Days to decision	86 days
Third-party review	No

APPLICANT

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

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