

**K861575 DIRECTATEX STREP A**Jun 3, 1986  
36 days to decisionK861575 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k861575/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Apr 28, 1986
Decision date	Jun 3, 1986
Days to decision	36 days
Third-party review	No

**APPLICANT**

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Company	<b>Pacific Biotech, Inc.</b>
Location	Mchenry, IL, US
Contact	SHU-CHING CHENG
510(k) history	29 submissions · 29 cleared · 1983-1993

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