

K982373 UNI-GOLD STREP A TEST KITFeb 11, 1999
219 days to decisionK982373 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k982373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jul 7, 1998
Decision date	Feb 11, 1999
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trinity Biotech, Plc
Location	Jamestown, NY, US
Contact	Erika B Ammirati
510(k) history	5 submissions · 5 cleared · 1999-2002

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