

K011709 UNI-GOLD STREP A TEST KITNov 8, 2001
157 days to decisionK011709 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k011709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Jun 4, 2001
Decision date	Nov 8, 2001
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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