

**K023766 ACON STREP A TWIST TEST DEVICE**Feb 10, 2003  
90 days to decisionK023766 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k023766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Nov 12, 2002
Decision date	Feb 10, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acon Laboratories Co.</b>
Location	San Diego, CA, US
Contact	EDWARD TUNG
510(k) history	6 submissions · 6 cleared · 1998-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k023766/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 23, 2026