

K010582 ACON STREP A RAPID TEST STRIPMay 7, 2001
69 days to decisionK010582 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k010582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Feb 27, 2001
Decision date	May 7, 2001
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acon Laboratories Co.
Location	San Diego, CA, US
Contact	ROBERT HUDAK
510(k) history	6 submissions · 6 cleared · 1998-2009

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