

K011097 QUICKVUE DIPSTICK STREP AMay 8, 2001
27 days to decisionK011097 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k011097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Apr 11, 2001
Decision date	May 8, 2001
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corp.
Location	Washington, DC, US
Contact	Robin Weiner
510(k) history	93 submissions · 93 cleared · 1983-2013

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