

**K171976 Sofia Strep A+ FIA, Sofia 2 Analyzer**Dec 21, 2017  
174 days to decisionK171976 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k171976/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jun 30, 2017
Decision date	Dec 21, 2017
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quidel Corporation</b>
Location	San Diego, CA, US
Contact	Edward C. Brehm
510(k) history	37 submissions · 35 cleared · 2010-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171976/> 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 May 14, 2026