

**K123793 SOFIA STREP A FIA**Jun 17, 2013  
189 days to decisionK123793 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k123793/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Dec 10, 2012
Decision date	Jun 17, 2013
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123793/> 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 8, 2026