

K141775 SOFIA (R) STREP A+ FIADec 16, 2014
168 days to decisionK141775 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k141775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jul 1, 2014
Decision date	Dec 16, 2014
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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