

**K130398 SOFIA(R) RSV FIA**Aug 13, 2013  
175 days to decisionK130398 · Product code: **GQG** · Microbiology  
Source: <https://www.510kdatabase.net/k130398/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Controls), Respiratory Syncytial Virus (GQG)
Date received	Feb 19, 2013
Decision date	Aug 13, 2013
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quidel Corp.</b>
Location	Washington, DC, US
Contact	JOHN D TAMERIUS, PH.D.
510(k) history	93 submissions · 93 cleared · 1983-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130398/> 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