

K162911 Sofia RSV FIA on Sofia 2 analyzerFeb 22, 2017
128 days to decisionK162911 · Product code: **GQG** · Microbiology
Source: <https://www.510kdatabase.net/k162911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Controls), Respiratory Syncytial Virus (GQG)
Date received	Oct 17, 2016
Decision date	Feb 22, 2017
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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