

K131606 SOFIA INFLUENZA A+B FIAJul 5, 2013
32 days to decisionK131606 · Product code: **GNX** · Microbiology
Source: <https://www.510kdatabase.net/k131606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Antigens, Cf (including Cf Control), Influenza Virus A, B, C (GNX)
Date received	Jun 3, 2013
Decision date	Jul 5, 2013
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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