

**K173250 Solana GBS Assay**Dec 21, 2017  
72 days to decisionK173250 · Product code: **NJR** · Microbiology  
Source: <https://www.510kdatabase.net/k173250/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen Test (NJR)
Date received	Oct 10, 2017
Decision date	Dec 21, 2017
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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