

K133503 AMPLIVUE GBS ASSAYDec 20, 2013
36 days to decisionK133503 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k133503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen Test (NJR)
Date received	Nov 14, 2013
Decision date	Dec 20, 2013
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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