

K182467 Simplexa GBS Direct, Simplexa GBS Positive Control PackNov 7, 2018
58 days to decisionK182467 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k182467/>**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	Sep 10, 2018
Decision date	Nov 7, 2018
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diasorin Molecular, LLC
Location	Cypress, CA, US
Contact	Sharon Young
510(k) history	13 submissions · 12 cleared · 2018-2025

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