

K181156 Panther Fusion GBS AssayJul 27, 2018
87 days to decisionK181156 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k181156/>**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	May 1, 2018
Decision date	Jul 27, 2018
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diagenode
Location	Seraing, BE
Contact	Geraldine Poncin
510(k) history	1 submissions · 1 cleared · 2018-2018

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