

**K173725 NeuMoDx GBS Assay**Jun 26, 2018  
203 days to decisionK173725 · Product code: **NJR** · Microbiology  
Source: <https://www.510kdatabase.net/k173725/>**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	Dec 5, 2017
Decision date	Jun 26, 2018
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neumodx Molecular, Inc.</b>
Location	Ann Arbor, MI, US
Contact	Kay Fuller
510(k) history	2 submissions · 2 cleared · 2018-2023

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