

K111860 BD MAX GBS ASSAY, BD MAX INSTRUMENTFeb 16, 2012
231 days to decisionK111860 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k111860/>**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	Jun 30, 2011
Decision date	Feb 16, 2012
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson & CO
Location	Franklin Lakes, NJ, US
Contact	MARY ANNE WILLIAMS
510(k) history	190 submissions · 190 cleared · 2001-2016

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