

K143312 Portrait GBS AssayApr 21, 2015
154 days to decisionK143312 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k143312/>**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 18, 2014
Decision date	Apr 21, 2015
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Great Basin Corporation
Location	Salt Lake City, UT, US
Contact	Chuck Owen
510(k) history	1 submissions · 1 cleared · 2015-2015

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