

K170557 GenePOC GBS LBMay 25, 2017
90 days to decisionK170557 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k170557/>**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	Feb 24, 2017
Decision date	May 25, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genepoc, Inc.
Location	Quebec, CA
Contact	Guy Sevigny
510(k) history	5 submissions · 5 cleared · 2017-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026