

**K121044 ILLUMIGENE GROUP B STREPTOCOCCUS CARROT
BROTH CLAIM**May 1, 2012
25 days to decisionK121044 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k121044/>**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	Apr 6, 2012
Decision date	May 1, 2012
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meridian Bioscience, Inc.
Location	Cincinnati, OH, US
Contact	Michelle L Smith
Website	https://www.meridianbioscience.com
510(k) history	38 submissions · 37 cleared · 2003-2025

Meridian Bioscience, Inc. is a diagnostic and life science solutions company with a manufacturing facility in Cincinnati, US. The company develops integrated diagnostic products and molecular reagents for clinical and research applications. Meridian has received FDA 510(k) clearances from total submissions since 2003. The company specializes exclusively in Microbiology devices, including molecular detection assays, pathogen identification systems, and diagnostic analyzers. The latest clearance in 2025 reflects continued regulatory activity and product innovation. Recent c...

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Device record: <https://www.510kdatabase.net/k121044/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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