

K022504 IDI-STREP B ASSAYNov 18, 2002
112 days to decisionK022504 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k022504/>**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	Jul 29, 2002
Decision date	Nov 18, 2002
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infectio Diagnostic, Inc.
Location	Baldwin, MD, US
Contact	Judi Smith
510(k) history	1 submissions · 1 cleared · 2002-2002

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