

K090191 HANDYLAB GBS ASSAY, HANDYLAB JAGUAR INSTRUMENT, HANDYLAB DNA EXTRACTION STRIP, HANDYLAB E3 EXTRACTION REAGENT, HANDYLABMay 27, 2010
485 days to decisionK090191 · Product code: **NJR** · Microbiology
Source: <https://www.510kdatabase.net/k090191/>**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	Jan 27, 2009
Decision date	May 27, 2010
Days to decision	485 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Handylab, Inc.
Location	Ann Arbor, MI, US
Contact	MARTHA J RUMFORD
510(k) history	1 submissions · 1 cleared · 2010-2010

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