

K920274 DIRECTIGEN NEISSERIA MENINGITIDIS TESTMar 18, 1992
56 days to decisionK920274 · Product code: **GTI** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, All Groups, N. Meningitidis (GTI)
Date received	Jan 22, 1992
Decision date	Mar 18, 1992
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
Contact	ROBERT E JAMES
510(k) history	632 submissions · 625 cleared · 1976-2001

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