

K950167 PREMIER EHECApr 14, 1995
87 days to decisionK950167 · Product code: **GNA** · Microbiology
Source: <https://www.510kdatabase.net/k950167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Types, Escherichia Coli (GNA)
Date received	Jan 17, 1995
Decision date	Apr 14, 1995
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meridian Diagnostics, Inc.
Location	Walker, MI, US
Contact	ALLEN D NICKOL
510(k) history	92 submissions · 92 cleared · 1980-1999

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