

K071799 MODIFICATION TO BIOSTAR OIA SHIGATOXOct 2, 2007
92 days to decisionK071799 · Product code: **GNA** · Microbiology
Source: <https://www.510kdatabase.net/k071799/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Types, Escherichia Coli (GNA)
Date received	Jul 2, 2007
Decision date	Oct 2, 2007
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Iverness Medical Professional Diagnostics
Location	Louisville, CO, US
Contact	ROBIN C HART
510(k) history	1 submissions · 1 cleared · 2007-2007

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