

K061889 BIOSTAR OIA SHIGATOXDec 12, 2006
162 days to decisionK061889 · Product code: **GMZ** · Microbiology
Source: <https://www.510kdatabase.net/k061889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Types, Escherichia Coli (GMZ)
Date received	Jul 3, 2006
Decision date	Dec 12, 2006
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inverness Medical-Biostar, Inc.
Location	Louisville, CO, US
Contact	ROBIN C HART
510(k) history	1 submissions · 1 cleared · 2006-2006

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