

K974461 TRIAGE CARDIAC CONTROLS, TRIAGE TROPONIN-I CONTROL, TRIAGE CK-MB CONTROL, TRIAGE MYOGLOBIN CONTROLDec 10, 1997
15 days to decisionK974461 · Product code: **JJT** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Nov 25, 1997
Decision date	Dec 10, 1997
Days to decision	15 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biosite Incorporated
Location	San Diego, CA, US
Contact	JOHN F BRUNI
510(k) history	46 submissions · 45 cleared · 1990-2010

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