

**K974881 TRIAGE C. DIFFICILE, TRIAGE C. DIFFICILE PANEL,
TRIAGE C. DIFFICILE TOXIN A**Mar 20, 1998
80 days to decisionK974881 · Product code: **MCB** · Microbiology
Source: <https://www.510kdatabase.net/k974881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, C. Difficile (MCB)
Date received	Dec 30, 1997
Decision date	Mar 20, 1998
Days to decision	80 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974881/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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