

**K904329 CLOSTRIDIUM DIFFICILE TOXIN A ENZYME
IMMUNOASSAY**Mar 12, 1991
173 days to decisionK904329 · Product code: **MCB** · Microbiology
Source: <https://www.510kdatabase.net/k904329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, C. Difficile (MCB)
Date received	Sep 20, 1990
Decision date	Mar 12, 1991
Days to decision	173 days
Third-party review	No

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	TOM TROTTER
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904329/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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