

K981098 STRATUS CS CARDIAC TROPONIN I TESTPAKApr 27, 1998
32 days to decisionK981098 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k981098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Mar 26, 1998
Decision date	Apr 27, 1998
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	CAROLYN K GEORGE
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981098/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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