

K973650 TROPONIN (TROP) METHODOct 20, 1997
25 days to decisionK973650 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k973650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Sep 25, 1997
Decision date	Oct 20, 1997
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Chemistry Systems, Inc.
Location	Newark, DE, US
Contact	REBECCA S AYASH
510(k) history	13 submissions · 13 cleared · 1996-1997

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