

K964862 TROPONIN-I TEST SYSTEMFeb 10, 1997
68 days to decisionK964862 · Product code: **MMI** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Dec 4, 1996
Decision date	Feb 10, 1997
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Intl., Inc.
Location	Deerfield, IL, US
Contact	RADHA GOOLABSINGH
510(k) history	30 submissions · 30 cleared · 1995-1998

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