

K050975 NANO-CHECK AMI 3 IN 1 CARDIAC DISEASE TEST FOR CARDIAC TROPONIN I, CREATINE KINASE MB AND MYOGLOBINMar 2, 2006
318 days to decisionK050975 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k050975/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Apr 18, 2005
Decision date	Mar 2, 2006
Days to decision	318 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nano-Ditech Co.
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	2 submissions · 2 cleared · 2005-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050975/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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