

**K053577 DIMENSION VISTA CTNI FLEX FLEX REAGENT
CARTRIDGE, CALIBRATOR AND SDIL SAMPLE DILUENT**Apr 14, 2006
113 days to decisionK053577 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k053577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Dec 22, 2005
Decision date	Apr 14, 2006
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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