

**K053531 DIMENSION VISTA FREE THYROXINE FLEX REAGENT
CARTRIDGE AND LOCI 1 CALIBRATOR**Mar 3, 2006
74 days to decisionK053531 · Product code: CEC · Chemistry
Source: <https://www.510kdatabase.net/k053531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Dec 19, 2005
Decision date	Mar 3, 2006
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	LORRAINE H PIESTRAK
510(k) history	343 submissions · 343 cleared · 1978-2010

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