

**K071597 DIMENSION VISTA (R) AFP FLEX(R) REAGENT
CARTRIDGE, MODEL K6454, DIMENSION VISTA (R) LOCI 5
CALIBRATOR, MODEL KC600**Jun 4, 2008
358 days to decisionK071597 · Product code: LOJ · Immunology
Source: <https://www.510kdatabase.net/k071597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Jun 12, 2007
Decision date	Jun 4, 2008
Days to decision	358 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	PAMELA A JURGA
510(k) history	343 submissions · 343 cleared · 1978-2010

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