

**K071603 DIMENSION VISTA CARCINOEMBRYONIC ANTIGEN
FLEX REAGENT CARTRIDGE (CEA)**Jun 25, 2008
379 days to decisionK071603 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k071603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Jun 12, 2007
Decision date	Jun 25, 2008
Days to decision	379 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	KATHLEEN DRAY-LYONS
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026