

K081615 OLYMPUS CEA - CARCINOEMBRYONIC ANTIGENMar 18, 2009
282 days to decisionK081615 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k081615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Jun 9, 2008
Decision date	Mar 18, 2009
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	STEPHANIE G DONNELLY
510(k) history	149 submissions · 149 cleared · 1994-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081615/> 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 May 18, 2026