

**K991707 MODIFICATION TO ACCESS CEA REAGENTS FOR USE ON THE ACCESS IMMUNOASSAY ANALYZER, MODELS 33200, 33205, 33209, 33206**

Jun 1, 1999  
13 days to decision

K991707 · Product code: **DHX** · Immunology  
Source: <https://www.510kdatabase.net/k991707/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	May 19, 1999
Decision date	Jun 1, 1999
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman</b>
Location	Brea, CA, US
Contact	ANGELA BYLAND
Website	<a href="http://www.beckmancoulter.com/">http://www.beckmancoulter.com/</a>
510(k) history	6 submissions · 6 cleared · 1989-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k991707/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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