

**K200215 ADVIA Centaur CEA Assay**Apr 13, 2020  
76 days to decisionK200215 · Product code: **DHX** · Immunology  
Source: <https://www.510kdatabase.net/k200215/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Jan 28, 2020
Decision date	Apr 13, 2020
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Disgnostics, Inc.</b>
Location	New York, NY, US
Contact	Mey Lyn Vasquez
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200215/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026