

**K200256 ADVIA Chemistry Enzymatic Hemoglobin Ale (A1c\_E)  
Assay**Jul 2, 2021  
515 days to decisionK200256 · Product code: **PDJ** · Chemistry  
Source: <https://www.510kdatabase.net/k200256/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Feb 3, 2020
Decision date	Jul 2, 2021
Days to decision	515 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics, Inc.</b>
Location	New York, NY, US
Contact	Julie Warren
Website	<a href="https://www.siemens-healthineers.com">https://www.siemens-healthineers.com</a>
510(k) history	152 submissions · 151 cleared · 2008-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200256/> 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 May 14, 2026