

**K173909 Dimension Hemoglobin A1c Assay**Jul 13, 2018  
203 days to decisionK173909 · Product code: **PDJ** · Chemistry  
Source: <https://www.510kdatabase.net/k173909/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Dec 22, 2017
Decision date	Jul 13, 2018
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173909/> 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 28, 2026