

**K160724 ADVIA Chemistry Creatine Kinase (CK\_L) Assay,  
ADVIA Chemistry Enzyme 3 Calibrator**Sep 7, 2016  
175 days to decisionK160724 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k160724/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Mar 16, 2016
Decision date	Sep 7, 2016
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics, Inc.</b>
Location	New York, NY, US
Contact	KATHLEEN DRAY-LYONS
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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