

**K042015 ADVIA CHEMISTRY GLUCOSE OXIDASE ASSAY AND  
ADVIA CHEMISTRY GLUCOSE HEXOKINASE**Sep 29, 2004  
64 days to decisionK042015 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k042015/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jul 27, 2004
Decision date	Sep 29, 2004
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bayer Healthcare, Diagnostics Division</b>
Location	New York, NY, US
Contact	ANDRES HOLLE
510(k) history	2 submissions · 2 cleared · 2004-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042015/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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