

**K052163 ADVIA IMS GLUCOSE ASSAY**Oct 11, 2005  
63 days to decisionK052163 · Product code: **CFR** · Chemistry  
Source: <https://www.510kdatabase.net/k052163/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Aug 9, 2005
Decision date	Oct 11, 2005
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bayer Healthcare, LLC</b>
Location	New York, NY, US
Contact	ANDRES HOLLE
510(k) history	46 submissions · 46 cleared · 2003-2018

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