

**K081731 DIMENSION CKI FLEX REAGENT CARTRIDGE,  
DIMENSION MBI FLEX REAGENT CARTRIDGE, AND CKI/MBI  
CALIBRATOR, MODELS DF38, DF32**Aug 29, 2008  
71 days to decisionK081731 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k081731/>**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	Jun 19, 2008
Decision date	Aug 29, 2008
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	VICTOR M CARRIO
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081731/>. 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