

**K083465 DIMENSION VISTA CREATINE KINASE FLEX
REAGENT CARTRIDGE AND DIMENSION VISTA CREATINE
KINASE MB FLEX REAGENT CARTRIDGE**Feb 27, 2009
95 days to decisionK083465 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k083465/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS) |
| Date received | Nov 24, 2008 |
| Decision date | Feb 27, 2009 |
| Days to decision | 95 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083465/> Data sourced from FDA 510(k) public records (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. - Generated May 28, 2026