

**K803301 CREATINE KINASE REAGENT**Jan 16, 1981  
17 days to decisionK803301 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k803301/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Dec 30, 1980
Decision date	Jan 16, 1981
Days to decision	17 days
Third-party review	No

**APPLICANT**

---

Company	<b>Gilford Diagnostics</b>
Location	Mchenry, IL, US
510(k) history	50 submissions · 50 cleared · 1978-1983

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k803301/> 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 14, 2026