

**K033058 CREATININE REAGENT KIT FOR BECKMAN  
SYNCHRON CX & CX DELTA SYSTEMS**Jan 30, 2004  
123 days to decisionK033058 · Product code: **CGX** · Chemistry  
Source: <https://www.510kdatabase.net/k033058/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Sep 29, 2003
Decision date	Jan 30, 2004
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Diamond Diagnostics, Inc.</b>
Location	Holliston, MA, US
Contact	LINDA M STUNDTNER
510(k) history	26 submissions · 26 cleared · 2001-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033058/> 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 June 29, 2026