

**K023407 ATAC PAK CREATININE REAGENT AND ATAC CALIBRATOR**Feb 14, 2003  
127 days to decisionK023407 · Product code: **CGX** · Chemistry  
Source: <https://www.510kdatabase.net/k023407/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Oct 10, 2002
Decision date	Feb 14, 2003
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Elan Diagnostics</b>
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	13 submissions · 13 cleared · 1999-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k023407/>; 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 June 29, 2026