

**K000556 ATAC PAK GLUCOSE REAGENT AND ATAC CALIBRATOR KITS**May 17, 2000  
89 days to decisionK000556 · Product code: **CFR** · Chemistry  
Source: <https://www.510kdatabase.net/k000556/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Feb 18, 2000
Decision date	May 17, 2000
Days to decision	89 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/k000556/> 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 30, 2026