

**K936212 GLUCOFILM TEST STRIPS**May 10, 1994  
133 days to decisionK936212 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k936212/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 28, 1993
Decision date	May 10, 1994
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Heraeus Kulzer, Inc.</b>
Location	Elkhart, IN, US
Contact	ROSANNE M SAVOL
510(k) history	145 submissions · 145 cleared · 1988-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k936212/> 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 20, 2026