

K926360 GLUCOFILM TEST STRIPSSep 8, 1993
261 days to decisionK926360 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k926360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 21, 1992
Decision date	Sep 8, 1993
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k926360/> 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 May 20, 2026