

**K940577 GLUCOMETER ELITE LOW CONTROL**Jun 13, 1994  
125 days to decisionK940577 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k940577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Feb 8, 1994
Decision date	Jun 13, 1994
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940577/> 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