

**K961807 CERTAIN HCT LEVEL A & LEVEL B/CVM HCT LEVELS  
1,2,3, & 4**

Jul 26, 1996  
77 days to decision

K961807 · Product code: **GLK** · Chemistry  
Source: <https://www.510kdatabase.net/k961807/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Hematocrit (GLK)
Date received	May 10, 1996
Decision date	Jul 26, 1996
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ciba Corning Diagnostics Corp.</b>
Location	East Walpole, MA, US
Contact	William J Pignato
510(k) history	125 submissions · 125 cleared · 1986-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k961807/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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