

**K850386 SYSTEM 8000 CELL COUNTER**May 2, 1985  
90 days to decisionK850386 · Product code: **GKL** · Hematology  
Source: <https://www.510kdatabase.net/k850386/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Feb 1, 1985
Decision date	May 2, 1985
Days to decision	90 days
Third-party review	No

**APPLICANT**

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Company	<b>Baker Instructions Corp.</b>
Location	Mchenry, IL, US
Contact	TOMALESKY
510(k) history	10 submissions · 10 cleared · 1981-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850386/>; 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 June 29, 2026