

**K032214 MEDONIC CA620/530 HEMATOLOGY ANALYZER**Jan 29, 2004  
192 days to decisionK032214 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k032214/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jul 21, 2003
Decision date	Jan 29, 2004
Days to decision	192 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Boule Medical AB</b>
Location	Plantation, FL, US
Contact	ANDREW SWANSON
510(k) history	2 submissions · 2 cleared · 2004-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032214/> 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 23, 2026