

K083420 MEDONIC M SERIESFeb 3, 2009
76 days to decisionK083420 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k083420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Counter, Differential Cell (GKZ)
Date received	Nov 19, 2008
Decision date	Feb 3, 2009
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boule Medical AB
Location	Plantation, FL, US
Contact	MICHAEL ELLIOTT
510(k) history	2 submissions · 2 cleared · 2004-2009

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