

**K981427 STAT PROFILE M ANALYZER**May 12, 1998  
26 days to decisionK981427 · Product code: **GKF** · Hematology  
Source: <https://www.510kdatabase.net/k981427/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Hematocrit, Automated (GKF)
Date received	Apr 16, 1998
Decision date	May 12, 1998
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Nova Biomedical Corp.</b>
Location	Mchenry, IL, US
Contact	PAUL W MACDONALD
510(k) history	89 submissions · 89 cleared · 1977-2011

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