

K981426 STAT PROFILE ULTRA F,G,H,I,J,K, AND L ANALYZERS

May 12, 1998
26 days to decision

K981426 · Product code: **GKF** · Hematology
Source: <https://www.510kdatabase.net/k981426/>

SUBMISSION DETAILS

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

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

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Device record: <https://www.510kdatabase.net/k981426/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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