

K964452 HEMATACHEKFeb 20, 1997
106 days to decisionK964452 · Product code: **GLK** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Hematocrit (GLK)
Date received	Nov 6, 1996
Decision date	Feb 20, 1997
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Richmond Diagnostics, Inc.
Location	New Brunswick, NJ, US
Contact	JOSEPH P PINENO
510(k) history	1 submissions · 1 cleared · 1997-1997

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