

K945854 B-FACT, BORDERLINE FACTOR ASSAY CONTROLOct 24, 1995
344 days to decisionK945854 · Product code: **GGN** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Nov 14, 1994
Decision date	Oct 24, 1995
Days to decision	344 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	George King Bio-Medical, Inc.
Location	Overland Park, KS, US
Contact	JUDITH A GILLISSEN
510(k) history	5 submissions · 5 cleared · 1995-2017

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