

K971858 SIGMA DIAGNOSTICS FIBRINOGEN KIT (886A/887A)Oct 9, 1997
142 days to decisionK971858 · Product code: **KQJ** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Fibrinogen Determination (KQJ)
Date received	May 20, 1997
Decision date	Oct 9, 1997
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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