

K840211 FIBRI-PREST AUTOMATE HA34Mar 2, 1984
43 days to decisionK840211 · Product code: **KQJ** · Hematology
Source: <https://www.510kdatabase.net/k840211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Fibrinogen Determination (KQJ)
Date received	Jan 19, 1984
Decision date	Mar 2, 1984
Days to decision	43 days
Third-party review	No

APPLICANT

Company	Wellcome Diagnostics
Location	Walker, MI, US
510(k) history	28 submissions · 28 cleared · 1983-1992

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Device record: <https://www.510kdatabase.net/k840211/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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