

K854384 ASSERACHROM FPA KITFeb 4, 1986
97 days to decisionK854384 · Product code: **DAN** · Hematology
Source: <https://www.510kdatabase.net/k854384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinopeptide A, Antigen, Antiserum, Control (DAN)
Date received	Oct 30, 1985
Decision date	Feb 4, 1986
Days to decision	97 days
Third-party review	No

APPLICANT

Company	American Bioproducts Co.
Location	Parsippany, NJ, US
Contact	B LE
510(k) history	79 submissions · 75 cleared · 1985-1998

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