

**K854015 FS TEST KIT**Mar 6, 1986  
160 days to decisionK854015 · Product code: **JBN** · Hematology  
Source: <https://www.510kdatabase.net/k854015/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Monomer Paracoagulation (JBN)
Date received	Sep 27, 1985
Decision date	Mar 6, 1986
Days to decision	160 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854015/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026