

**K884384 THROMBIN-PREST REAGENT KIT**Dec 28, 1988  
71 days to decisionK884384 · Product code: **GJA** · Hematology  
Source: <https://www.510kdatabase.net/k884384/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Thrombin Time (GJA)
Date received	Oct 18, 1988
Decision date	Dec 28, 1988
Days to decision	71 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884384/>; 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