

**K781880 ASSAY KIT, THROMBO-SCREEN**Dec 4, 1978  
28 days to decisionK781880 · Product code: **GIS** · Hematology  
Source: <https://www.510kdatabase.net/k781880/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Nov 6, 1978
Decision date	Dec 4, 1978
Days to decision	28 days
Third-party review	No

**APPLICANT**

---

Company	<b>Pacific Hemostasis</b>
Location	Mchenry, IL, US
510(k) history	29 submissions · 29 cleared · 1978-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k781880/> 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