

**K984129 COAGULATION CONTROL LEVEL 1 (NORMAL)**Dec 1, 1998  
13 days to decisionK984129 · Product code: **GIZ** · Hematology  
Source: <https://www.510kdatabase.net/k984129/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Control, Normal (GIZ)
Date received	Nov 18, 1998
Decision date	Dec 1, 1998
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984129/> 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