

**K971428 COAGULATION CONTROL  
PLASMA(ABNORMAL)LEVEL 0**

Jun 17, 1997  
61 days to decision

K971428 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k971428/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Apr 17, 1997
Decision date	Jun 17, 1997
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k971428/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026