

K984130 COAGULATION CONTROL LEVEL 2 (ABNORMAL)Dec 1, 1998
13 days to decisionK984130 · Product code: **GGC** · Hematology
Source: <https://www.510kdatabase.net/k984130/>**SUBMISSION DETAILS**

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

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984130/> 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