

K991439 POLLER CALIBRANTSDec 20, 1999
238 days to decisionK991439 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k991439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Apr 26, 1999
Decision date	Dec 20, 1999
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	European Concerted Action on Anticoagulation
Location	Manchester, GB
Contact	L. POLLER
510(k) history	1 submissions · 1 cleared · 1999-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991439/> 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