

K971748 TAS PT-NCTEST CONTROLSMay 29, 1997
17 days to decisionK971748 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k971748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	May 12, 1997
Decision date	May 29, 1997
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Diagnostics, Inc.
Location	Raleigh, NC, US
Contact	James M Clinton
510(k) history	13 submissions · 13 cleared · 1995-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971748/> 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