

**K981178 THROMBOLYTIC ASSESSMENT SYSTEM LOW
RANGE HEPARIN MANAGEMENT TEST CONTROLS**Apr 27, 1998
26 days to decisionK981178 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k981178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Apr 1, 1998
Decision date	Apr 27, 1998
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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